EXHIBIT C

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	**MDL NO. 16-2738 (FLW) (LHG)**

THIS DOCUMENT RELATES TO ALL CASES

PLAINTIFFS' SECOND AMENDED MASTER LONG FORM COMPLAINT AND JURY DEMAND

Plaintiffs, by and through their counsel and pursuant to Case Management Order No. 1 ("CMO-1"), bring this Second Amended Master Long Form Complaint against Defendants Johnson & Johnson ("J&J") and Johnson & Johnson Consumer Inc. f/k/a Johnson & Johnson Consumer Companies, Inc. ("J&J Consumer"), Imerys Talc America, Inc. f/k/a Luzenac America, Inc., f/k/a Rio Tinto Minerals, Inc. ("Imerys Talc")[1] and Personal Care Products Council f/k/a Cosmetic, Toiletry, and Fragrance Association ("PCPC") (collectively referred to as "Defendants").

This Second Amended Master Long Form Complaint sets forth allegations and questions of fact and law common to those claims subsumed within the context of this multidistrict proceeding. Plaintiffs seek compensatory and punitive damages, monetary restitution, equitable relief, and all other available remedies as a result of injuries incurred by Defendants' defective products. Plaintiffs make the following allegations based upon their personal knowledge and upon

[1] Imerys Talc filed for Chapter 11 bankruptcy protection on February 13, 2019. *See In re: Imerys Talc America, Inc.*, 19-10289-LSS, USBC, District of Delaware. Imerys Talc is named as a Defendant in this Second Amended Master Long Form Complaint solely because it relates back to cases filed against Imerys before the bankruptcy petition. This Second Amended Long Form Complaint does not assert new claims against Imerys Talc.

information and belief, as well as upon their attorneys' investigative efforts, regarding Defendants' talcum powder-containing products known as Johnson's Baby Powder and Shower to Shower (hereinafter together or individually, "the PRODUCTS").

This Second Amended Master Long Form Complaint does not necessarily include all claims asserted in all of the transferred actions to this Court, nor is it intended to consolidate for any purpose the separate claims of the Plaintiffs herein. It is anticipated that individual plaintiffs may adopt this Second Amended Master Long Form Complaint and the necessary causes of action herein through use of a separate Short Form Complaint. Any separate facts and additional claims of individual plaintiffs are set forth in those actions filed by the respective plaintiffs. This Second Amended Master Long Form Complaint does not constitute a waiver or dismissal of any actions or claims asserted in those individual actions, nor does any plaintiff relinquish the right to move to amend their individual claims to seek any additional claims as discovery proceeds. As more particularly set forth herein, each plaintiff maintains that the PRODUCTS are defective, dangerous to human health, unfit and unsuitable to be advertised, marketed and sold in the United States, and lack proper warnings associated with their use.

PARTIES

1. Pursuant to CMO-1, this Second Amended Master Long Form Complaint is filed for all Plaintiffs and, if applicable, Plaintiffs' spouses, children, decedents, estates or wards represented by Plaintiffs' counsel who file a Short Form Complaint. By operation of CMO-1, all allegations pleaded herein are deemed pleaded in any Short Form Complaint.

2. Plaintiffs were diagnosed with various forms of cancer of the female reproductive system, including epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer, which were directly and proximately caused by their regular and prolonged exposure to talcum powder contained in the PRODUCTS.

3. Defendant, Johnson & Johnson, is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Johnson & Johnson may be served with process by serving its registered agent at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

4. At all relevant times, Johnson & Johnson was engaged in the business of manufacturing, formulating, marketing, testing, promoting, selling, and/or distributing the PRODUCTS. At all relevant times, Johnson & Johnson regularly transacted, solicited, and conducted business in all fifty states of the United States.

5. Defendant Johnson & Johnson Consumer Inc. f/k/a Johnson & Johnson Consumer Companies, Inc. is a New Jersey corporation with its principal place of business in the State of New Jersey. Johnson & Johnson Consumer Inc. may be served with process by serving its registered agent located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

6. At all relevant times, upon information and belief, Johnson & Johnson Consumer Inc. was engaged in the business of manufacturing, formulating, marketing, testing, promoting, selling, and/or distributing the PRODUCTS. At all relevant times, Johnson & Johnson Consumer Inc. regularly transacted, solicited, and conducted business in all fifty states of the United States.

7. At all relevant times, Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc. have engaged in the research, development, formulation, manufacture, design, testing, licensing, sale, distribution, marketing and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the PRODUCTS.

8. Defendant Johnson & Johnson Consumer Inc. is and has been at all relevant times a wholly-owned subsidiary of Defendant Johnson & Johnson, under the complete dominion of and control of Defendant Johnson & Johnson. Hereinafter, unless otherwise delineated, these two entities together shall be referred to as the "Johnson & Johnson Defendants."

9. Defendant Imerys Talc America, Inc., f/k/a Luzenac America, Inc., f/k/a Rio Tinto Minerals, Inc. (hereinafter, "Imerys Talc"), is a Delaware corporation with its principal place of business in the State of California, located at 1732 North First Street, Suite 450, San Jose, CA 95112. At all relevant times, Imerys Talc has maintained a registered agent in the State of Delaware. Imerys Talc may be served with process of this Court via service on its registered agent, Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19801.

10. At all relevant times, upon information and belief, Imerys Talc has been in the business of mining and distributing talc for use in talcum powder-based products, including the PRODUCTS. Imerys Talc is the successor or continuation of Luzenac America, Inc. and Rio Tinto Minerals, Inc. Imerys Talc is legally responsible for the conduct of Luzenac America, Inc. and Rio Tinto Minerals, Inc.

11. Defendant Personal Care Products Council ("PCPC") f/k/a Cosmetic, Toiletry, and Fragrance Association ("CTFA"), is a corporation organized under the laws of the District of Columbia, with its principal place of business in the District of Columbia. At all relevant times, upon information and belief, Imerys Talc and Johnson & Johnson have been active members of PCPC. PCPC may be served with process of this Court via service on its registered agent, Thomas Myers, at 1620 L Street, N.W., Suite 1200, Washington, District of Columbia 20036. PCPC is the successor or continuation of CTFA, and PCPC is legally responsible for CTFA's conduct.

12. At all relevant times, upon information and belief, PCPC was a national trade association representing the personal care and cosmetics industry for the purposes of and, in fact, interacting with and influencing local, state and federal governmental agencies on issues related to, among other things, the regulation, testing and marketing of talc based body powders and the PRODUCTS. The actions of Defendant PCPC have had repercussions throughout the talc industry, and in all states of the United States.

13. Beyond acting as a trade association, as alleged herein, PCPC actively engaged in actions that directly impacted the marketing and sale of the PRODUCTS.

14. Defendants John Does/Jane Does 1-30 are those persons, agents, employees, and/or representatives of Defendants whose conduct as described herein caused or contributed to the damages of Plaintiffs, all of whose names and legal identities are unknown to Plaintiffs at this time, but will be substituted by amendment when ascertained, individually and jointly.

15. Defendants Unknown Businesses and/or Corporations A-Z are unknown entities whose conduct as described herein caused or contributed to the damages of Plaintiffs, all of whose names and legal identities are unknown to Plaintiffs at this time, but will be substituted by amendment when ascertained, individually and jointly.

JURISDICTION AND VENUE

16. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(d) because complete diversity exists between Plaintiffs and Defendants.

17. The amount in controversy alleged by each of the respective individual Plaintiffs will exceed the sum or value of $75,000.

18. Defendants have significant contacts with the federal judicial districts identified in the Short Form Complaints such that they are subject to the personal jurisdiction of the court in said districts.

19. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in the federal judicial districts identified in the Short Form Complaints. Pursuant to 28 U.S.C. § 1391(a), venue is proper in said districts.

FACTUAL ALLEGATIONS

I. Overview of Talc & the Products

20. Talc is an inorganic magnesium silicate mineral that may occur in a variety of forms (massive or platy, foliated, and fibrous).

21. Talc is used in a wide array of industrial, commercial and cosmetic substances. It is the main substance in talcum powders, talc-based body powders, and the PRODUCTS.

22. Talc is mined from deposits in the earth that can contain asbestos, heavy metals (nickel, cadmium, cobalt, chromium, arsenic, etc.), and other toxic minerals.

23. The Johnson & Johnson Defendants manufactured the PRODUCTS.

24. Johnson & Johnson began the manufacture of Johnson's Baby Powder in approximately 1894.

25. In the early 1970, Johnson & Johnson incorporated its Baby Products Division (a/k/a Johnson & Johnson Baby Products Company) which took over the marketing of Johnson's Baby Powder.

26. In the 1990s, the Baby Products Division became Johnson & Johnson Consumer Products, Inc.; Johnson & Johnson Consumer Products, Inc. remained a division of Johnson & Johnson.

27. In 1997, Johnson & Johnson Consumer Products, Inc. changed its name to Johnson & Johnson Consumer Companies Inc. and operated under this name until approximately 2015, when its name was changed to Johnson & Johnson Consumer Inc., it remained a division of Johnson & Johnson.

28. During all relevant times, Johnson's Baby Powder® was composed primarily of talc along with other constituent elements found in talc such as asbestos, fibrous talc, and heavy metals (e.g., nickel, cadmium, cobalt, chromium, arsenic), and fragrance chemicals.

29. Johnson & Johnson began the manufacture of Shower to Shower in 1967.

30. Shower to Shower was manufactured through the same Johnson & Johnson divisions as Johnson's Baby Powder, until Shower to Shower was sold in 2012.

31. During all relevant times, Shower to Shower was composed of talc and cornstarch, along with other certain constituent elements found in talc such as asbestos, fibrous talc, and heavy metals (e.g., nickel, cadmium, cobalt, chromium, arsenic), and fragrance chemicals.

32. Johnson & Johnson obtained the talc for the PRODUCTS from various sources including Guangxi, China, the Fontana mine in the Germanasca Valley and Val Chisone region in Italy, as well as the Johnson, Hammondsville, Rainbow, Hamm, and Argonaut mines in Vermont (collectively referred to as "Vermont mines"). *See* **Exhibit 1** (2/15/2019 Musco Dep. 63:7–64:5) (Hammondsville and Johnson mines were sources of cosmetic talc for Johnson's Baby Powder); *see also* **Exhibit 2** (3/8/2019 Musco Dep. 451:2–453:22) (Emtal 500 from Johnson Mine used in Cosmetics); **Exhibit 3** (10/29/1982 Miller Dep.); *see also* **Exhibit 4** (Trial Testimony of John Hopkins, 7/22/19 *Barden et al. v. Johnson & Johnson* at 18:15-19:21).

33. From approximately 1967 until 2003, the primary source of talc for the PRODUCTS was Vermont mines including the Hammondsville, Rainbow, Hamm, and Argonaut mines. The mines were owned and operated by Johnson & Johnson's subsidiary, Windsor Minerals, with Johnson & Johnson exercising control over all key decisions concerning the mines.

34. In 1989, Johnson & Johnson sold the Vermont mines and mills used to supply talc for its talc products to Cyprus Mines Corporation ("Cyprus"). The mines sold to Cyprus remained the primary source of Johnson & Johnson's talc products until 2003.

35. Over time, the trade names for the talc ore used by Johnson & Johnson in Johnson's Baby Powder and Shower to Shower included "Emtal," "Grade 66," "Grade 96," "1615," "Italian 00000," and "Supra" all of which contain asbestos.

36. At all relevant times, a feasible and safe alternative to talc has existed. For example, cornstarch is an organic carbohydrate that is quickly broken down by the body with no known adverse health effects. Cornstarch powders have been sold and marketed for the same uses as the PRODUCTS with nearly the same effectiveness as talcum powders. **Exhibit 5** (JNJ 000011777). See **Exhibit 6** (JNJ 000331979), cornstarch "can be absorbed into the body, tending not to cause severe granuloma as may be the case with talc." See **Exhibit 7** (JNJ 000332195), Johnson's baby powder, pure cornstarch, being marketed as "a change for the better."

37. At all relevant times, Defendant Imerys Talc[2] mined, refined, screened, tested and delivered the raw talc contained in the PRODUCTS.

38. At relevant times, Imerys Talc continually advertised and marketed talc as safe for human use, and knew that its processed talc was intended for human use.

39. Beginning in 2006 and until the present, Imerys Talc supplied its customers, including the Johnson & Johnson Defendants, with Material Safety Data Sheets ("MSDS") for talc, which conveyed health and warning information about talc. *See* **Exhibit 7** (IMERYS 081218).[3]

40. At relevant times, the Johnson & Johnson Defendants advertised and marketed their "Johnson's Baby Powder" product as a symbol of "freshness" and "comfort," eliminating friction on the skin, absorbing "excess wetness" to keep skin feeling dry and comfortable, and "clinically proven gentle and mild." The Johnson & Johnson Defendants induced women through advertisements to dust themselves with this product to mask odors. The Johnson's Baby Powder

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2 All allegations regarding actions taken by Imerys Talc also include actions taken while that entity was known as Luzenac America, Inc.

3 All exhibits referenced in this Second Amended Master Long Form Complaint are appended hereto and incorporated by reference.

bottle specifically targets women, stating: "For you, use every day to help feel soft, fresh, and comfortable." *See* **Exhibit 8** (P-121 (excerpts from www.johnsonbaby.com and www.showertoshower.com); **Exhibit 9** (P-125 (JNJ 000058760)); and **Exhibit 10** (P-49 (picture of Johnson & Johnson's Baby Powder bottle)).

41. At relevant times, the Johnson & Johnson Defendants advertised and marketed their "Shower to Shower" product as safe for use by women as evidenced in its slogan, "A sprinkle a day keeps odor away," and through advertisements such as: "Your body perspires in more places than just under your arms. Use SHOWER to SHOWER to feel dry, fresh, and comfortable throughout the day;" and "SHOWER to SHOWER can be used all over your body." The website included the suggested use of the product "Shower to Shower" in the genital area with the following: "Soothe Your Skin: Sprinkle on problem areas to soothe skin that has been irritated from friction. Apply after a bikini wax to help reduce irritation and discomfort." *See* **Exhibit 8** (P-121 (excerpts from www.johnsonbaby.com and www.showertoshower.com); **Exhibit 10** (P-49 (picture of Johnson & Johnson's Baby Powder bottle)); and **Exhibit 11** (P-50 (picture of Johnson & Johnson's Shower to Shower bottle)).

42. Although the labels on the bottles for the Johnson & Johnson Baby Powder and Johnson & Johnson Shower to Shower products have changed over time, the core message has been the same: that women can safely use the products on their bodies including their genital areas.

II. Strong Scientific Evidence Links Talc Use to Ovarian Cancer

43. In a 1948 paper, Johnson & Johnson scientists recognized talc as a hazard to human health. Eberl et al., *Comparative Evaluation of the Effects of Talcum and a New Absorbable Substitute on Surgical Gloves*, 25 Am. J. Surgery 493 (1948).

44. As early as 1961, research established that some particles, including particles like talc, can translocate from the exterior genital area to the ovaries in women. Egli & Newton, *The Transport of Carbon Particles in the Human Female Reproductive Tract,* 12 Fertility Sterility 2 (1961).

45. In 1964, Johnson & Johnson admitted in an internal company document that talc could not be safely absorbed by the vagina while cornstarch could be. *See* **Exhibit 12** (P-343 (JNJ 000265536 at p. 3 (cornstarch "replaced talc because [cornstarch]. . . was found to be absorbed safely in the vagina whereas, of course, talc was not")). *See also*, **Exhibit 6** JNJ 000331979, cornstarch "can be absorbed into the body, tending not to cause severe granuloma as may be the case with talc."

46. Beginning in the 1970s, Johnson & Johnson had in its possession published scientific literature detailing specific cases involving consumers who developed extensive talcosis as a result of the liberal use of cosmetic powder. **Exhibit 13**, 11/28/2018 Musco Dep. 107:12–109:10.

47. In or about 1971, the first study was conducted that suggested an association between talc and ovarian cancer. This study was conducted by Dr. W.J. Henderson and others in Cardiff, Wales. *See* **Exhibit 14** (P-1 (Henderson, WJ, et al. Talc and carcinoma of the ovary and cervix. Journal of Obstetrics and Gynaecology of the British Commonwealth. March 1971. Vol. 78. pp. 266-271)). *See also* **Exhibit 15**, P-344 (JNJ 000327788), JNJ forwarded tissue samples from Dr. Henderson to Dr. Langer at Mt. Sinai who confirmed Dr. Henderson's observations.

48. In or about 1979, migration of particulates from the vagina to the peritoneal cavity and ovaries was found, correlating previous findings in surgically removed specimens. *See* **Exhibit 16** (JNJ 000005093).

49. In 1982, the first epidemiologic study was performed on talc powder use in the female genital area. This study was conducted by Dr. Daniel Cramer and others. *See* **Exhibit 17** (P-3 (JNJ000020733)). This study found a 92% increased risk of ovarian cancer with women who reported genital talc use. Upon information and belief, shortly after this study was published, Dr. Bruce Semple of Johnson & Johnson visited Dr. Cramer about his study. Dr. Cramer advised Dr. Semple that Johnson & Johnson should place a warning on its talcum powder products about the ovarian cancer risks so that women could make an informed decision about their health.

50. Since publication of the Cramer study in 1982, there have been dozens of additional epidemiologic and other scientific studies providing data regarding the association of talc and ovarian cancer. Nearly all of the epidemiology studies have reported an elevated risk for ovarian cancer associated with genital talc use in women. Significantly, scientific studies have provided biologically plausible explanations as to how genital talc use can cause ovarian cancer:

a. In 1983, a case-control study found a 150% increased risk of ovarian cancer for women who use talcum powder in the genital area. Hartge, P., *et al.* Talc and Ovarian Cancer. *JAMA*. 1983; 250(14):1844.

b. In 1988, a case control study of 188 women diagnosed with epithelial ovarian cancer and 539 control women found that 52% of the cancer patients habitually used talcum powder on the genital area before their cancer diagnosis. The study showed a 40% increase in risk of ovarian cancer in women that used talcum powder on their genital area and the relative risk for talc use between 1 and 9 years, relative to a shorter duration, was 1.6 (p = 0.05). Whittemore AS, *et al.* Personal and environmental characteristics related to epithelial ovarian cancer. II. Exposures to talcum powder, tobacco, alcohol, and coffee. *Am. J. Epidemiol.* 1988 Dec; 128(6):1228-40.

c. A 1989 study looked at 235 women diagnosed with epithelial ovarian cancer and 451 controls and found a 29% increased risk in ovarian cancer with women who reported genital talcum powder use more than once each week. Booth, M., *et al*. Risk factors for ovarian cancer: a case-control study. *Br J Cancer*. 1989 Oct; 60(4):592-8.

d. In 1992, a case-control study found an 80% increased risk of ovarian cancer in women with more than 10,000 lifetime perineal applications of talc, demonstrating a positive dose-response relationship. Harlow BL, *et al.* Perineal exposure to talc and ovarian cancer risk. *Obstet. Gynecol.* 1992 Jul; 80(1):19-26.

e. Another 1992 case-control study reported a 70% increased risk from genital talc use and a 379% significantly increased risk of ovarian cancer in women who used talc on sanitary napkins in their genital area. Rosenblatt, K.A. *et al.* Mineral fiber exposure and the development of ovarian cancer. *Gynecol. Oncol.* 1992 Apr; 45(1):20-5.

f. Yet another 1992 case-control study by Yong Chen with 112 diagnosed epithelial ovarian cancer cases and 224 age-matched community controls found an elevated risk for ovarian cancer in women who applied talc-containing dusting powder to the lower abdomen and perineum for longer than 3 months. Yong Chen, *et al.*, Risk Factors for Epithelial Ovarian Cancer in Beijing, China, 21 *Int. J. Epidemiol.* 23-29 (1992).

g. In 1995, the largest study of its kind to date found a 27% increased risk in ovarian cancer for women who regularly use talc in the abdominal or perineal area. Purdie, D., *et al.* Reproductive and other factors and risk of epithelial ovarian cancer: An

Australian case-control study. Survey of Women's Health Study Group. *Int. J. Cancer*. 1995 Sep 15; 62(6):678-84.

h. In 1996, a case-control study found a statistically significant 97% increased risk of ovarian cancer in women who used what they described as a "moderate" or higher use of talc-based powders in their genital area. *See* Shushan, A., *et al.* Human menopausal gonadotropin and the risk of epithelial ovarian cancer. *Fertil. Steril.* 1996 Jan; 65(1):13-8.

i. In 1997, a case control study of 313 women with ovarian cancer and 422 without this disease found that the women with cancer were more likely to have applied talcum powder to their external genitalia area. Women who performed any perineal dusting or used genital deodorant spray respectively had a statistically significant 60% to 90% higher risk of developing ovarian cancer. Cook, LS, *et al.* Perineal powder exposure and the risk of ovarian cancer. *Am. J Epidemiol.* 1997 Mar 1; 145(5):459-65.

j. In 1997, a case-control study involving over 1,000 women found a statistically significant increased risk of 42% for ovarian cancer for women who applied talc directly or via sanitary napkins to their perineal area. Chang, S, *et al.* Perineal talc exposure and risk of ovarian carcinoma. *Cancer*. 1997 Jun 15; 79(12):2396-401.

k. In 1998, a case-control study found a 149% increased risk of ovarian cancer in women who used talc-based powders on their perineal area. Godard, B., *et al.* Risk factors for familial and sporadic ovarian cancer among French Canadians: a case-control study. *Am. J. Obstet. Gynecol.* 1998 Aug; 179(2):403-10.

l. Dr. Daniel Cramer conducted another case-control study in 1999, observing 563 women newly diagnosed with epithelial ovarian cancer and 523 women in a

control. The study found a statistically significant 60% increased risk of ovarian cancer in women that used talc-based body powders on their perineal area and an 80% increase in risk for women with over 10,000 lifetime applications. Cramer, DW, *et al.* Genital talc exposure and risk of ovarian cancer. *Int. J. Cancer*. 1999 May 5; 81(3):351-56.

m. In 2000, a case-control study including over 2,000 women found a statistically significant 50% increased risk of ovarian cancer from genital talc use in women. Ness, RB, *et al.* Factors related to inflammation of the ovarian epithelium and risk of ovarian cancer. *Epidemiology*. 2000 Mar; 11(2):111-7.

n. In 2004, a case-control study of nearly 1,400 women from 22 counties in Central California found a statistically significant 37% increased risk of epithelial ovarian cancer from women's genital talc use, and a 77% increased risk of serous invasive ovarian cancer from women's genital talc use. Importantly, this study also examined women's use of cornstarch powders as an alternative to talc and found no increased risk of ovarian cancer in women in the cornstarch group, supporting a safe alternative to talc for genital use. Mills, PK, *et al.* Perineal talc exposure and epithelial ovarian cancer risk in the Central Valley of California. *Int. J. Cancer*. 2004 Nov 10; 112(3):458-64.

o. In a 2007 study by Buz'Zard, *et al.*, talc was found to increase proliferation, induce neoplastic transformation and increase reactive oxygen species (ROS) generation time-dependently in the ovarian cells. The study concluded that talc may contribute to ovarian carcinogenesis in humans. The data suggested that talc may contribute to ovarian neoplastic transformation and Pycnogenol reduced the talc-induced transformation. *Phytotherapy Research: PTR* 21, no. 6 (June 2007): 579–86.

p. In 2008, a combined study of over 3,000 women from a New England-based case-control study found a 36% statistically significant increased risk for all types of epithelial ovarian cancer from genital talc use and a 60% increased risk of the serous invasive ovarian cancer subtype. The study also found a highly significant dose-response relationship between the cumulative talc exposure and incidence of ovarian cancer (and all serous invasive ovarian cancer), adding further support to the causal relationship. Gates, MA, *et al.* Talc Use, Variants of the GSTM1, GSTT1, and NAT2 Genes, and Risk of Epithelial Ovarian Cancer. *Cancer Epidemiol Biomarkers Prev.* 2008 Sep; 17(9):2436-44.

q. A 2009 case-control study of over 1,200 women found the risk of ovarian cancer increased significantly with increasing frequency and duration of talc use, with an overall statistically significant 53% increased risk of ovarian cancer from genital talc use. That increased risk rose dramatically, to 108%, in women with the longest duration and most frequent talc use. Wu, AH, *et al.* Markers of inflammation and risk of ovarian cancer in Los Angeles County. *Int. J Cancer.* 2009 Mar 15; 124(6):1409-15.

r. In 2011, another case-control study of over 2,000 women found a 27% increased risk of ovarian cancer from genital talc use. Rosenblatt, KA, *et al.* Genital powder exposure and the risk of epithelial ovarian cancer. *Cancer Causes Control.* 2011 May; 22(5):737-42.

s. In June of 2013, a pooled analysis of over 18,000 women in eight case-control studies found a 20% to 30% increased risk of women developing epithelial ovarian cancer from genital powder use. The study concluded by stating, "Because there are few modifiable risk factors for ovarian cancer, avoidance of genital powders

may be a possible strategy to reduce ovarian cancer incidence." Terry, KL, *et al.* Genital powder use and risk of ovarian cancer: a pooled analysis of 8,525 cases and 9,859 controls. *Cancer Prev. Res. (Phila).* 2013 Aug; 6(8):811.

t. In May 2015, Roberta Ness performed a meta-analysis of all accumulated epidemiologic evidence (23 case-control studies, 5 meta-analyses, and 3 analyses of a single cohort). Talc use was found to increase ovarian cancer by 30-60% in almost all well-designed studies. The results were published in the International Journal of Gynecological Cancer. Ness, R. Does talc exposure cause ovarian cancer? Intl. J. Gyn. Cancer. 25 Supp. 1 (May 2015): 51.

u. Also in 2015, Cramer, *et a*l. performed a retrospective case-control study. Overall, genital talc use was associated with an OR (95% CI) of 1.33 (1.16, 1.52), with a trend for increasing risk by talc-years. In addition, subtypes of ovarian cancer more likely to be associated with talc included invasive serous and endometrioid tumors and borderline serous and mucinous tumors. Premenopausal women and postmenopausal HT users with these subtypes who had accumulated greater than 24 talc-years had ORs (95% CI) of 2.33 (1.32, 4.12) and 2.57 (1.51, 4.36), respectively. Epidemiology (Cambridge, Mass.), December 17, 2015.

v. A 2016 study of African American women found that body powder was significantly associated with epithelial ovarian cancer (EOC). Genital powder was associated with an increased risk of EOC (OR = 1.44; 95% CI, 1.11–1.86) and a dose–response relationship was found for duration of use and number of lifetime applications ($P < 0.05$). The study concluded that body powder is a modifiable risk factor for epithelial ovarian cancer among African American women. Schildkraut JM, et al. Association between Body Powder Use and Ovarian Cancer:

the African American Cancer Epidemiology Study (AACES). Cancer epidemiology, biomarkers & prevention: a publication of the American Association for Cancer Research, cosponsored by the American Society of Preventive Oncology. *Cancer Epidemiol Biomarkers Prev.; 25(10); 1411–7.*[4]

w. A 2016 study examined 2,041 cases with epithelial ovarian cancer and 2,100 age-and-residence-matched controls. Genital use of talc was associated with a 1.33 OR with a trend for increasing risk by years of talc use. Most women in the study reported using Johnson & Johnson's Baby Powder and Shower to Shower. Among epidemiologic variables, no confounders for the association were identified. Cramer DW, et al. The association between talc use and ovarian cancer: a retrospective case-control study in two US states. *Epidemiology*. 2016; 27, 334-46.

x. In 2018, two meta-analyses were published. These meta-analyses, which combined prior epidemiological studies, concluded that the use of talcum products increased the risk of ovarian cancer. *See* Penninkilampi, Ross, and Guy D. Eslick. *"Perineal Talc Use and Ovarian Cancer: A Systematic Review and Meta-Analysis."* Epidemiology (Cambridge, Mass.) 29, no. 1 (January 2018): 41–49; *see also* Berge, Wera, et al. *"Genital Use of Talc and Risk of Ovarian Cancer: A Meta-Analysis."* European Journal of Cancer Prevention, January 2017, 1.

y. In 2018, Saed, et al. found that talc effects the redox state in human ovarian cells, a known biological pathway to cause cancer. The scientists concluded that this

[4] Johnson & Johnson was aware of the high rate of usage among African Americans (52%) and among Hispanics (37.6%). **Exhibit 18** (P-10 (JNJ000021093)). Despite its knowledge of the increased risk of ovarian cancer, Johnson & Johnson targeted these populations in its marketing efforts. *Id.*

study demonstrated a cellular biological mechanism of how talc causes ovarian cancer. *See* Fletcher, NM, et al. *"Molecular Basis Supporting the Association of Talcum Powder Use with Increased Risk of Ovarian Cancer."* Reproductive Sciences 1-10 (2019).

z. In 2019, Taher et al. published a systematic review of the evidence linking talcum powder to ovarian cancer. This study concluded that "talc is a possible cause of cancer in humans based on the totality of evidence from multiple observational studies and a plausible biological pathway including chronic inflammation and oxidative stress." Taher et al., *Critical Review of the Association between Perineal Use of Talc Powder and Risk of Ovarian Cancer*, 90 Reproductive Toxicology 88, 99 (2019).

aa. In addition, over the past four decades, there have been numerous animal and human ovarian cell studies that show talc is harmful and can increase the risk of developing ovarian cancer.

III. Asbestos and Other Constituents in Talc

51. The PRODUCTS contain platy talc, fibrous talc, asbestos, heavy metals, and fragrance chemicals, and Defendants failed to warn the public, including Plaintiffs, about the fact that the PRODUCTS contained such carcinogenic substances.

52. Beginning in the 1930s, medical and scientific literature emerged indicating talc was commonly, if not invariably, contaminated with substances known or suspected of being carcinogenic, such as asbestos, silica, quartz, nickel and arsenic. Over the next several decades, a growing body of medical and scientific literature demonstrated that direct and secondary exposure to talc, including asbestos-containing talc, was hazardous to exposed persons' health in that it could cause lung disease, cancer and death.

53. The United States Geological Survey on Commercial Talc Production conducted in 1965, as well as those dating back to the 1800s, noted the presence of tremolite, anthophyllite and chrysotile commonly among those minerals found within talc deposits.

54. In 1968, a scientific study of store-bought, commercially available talcum powders conducted by the Occupational Health Program, National Center for Urban Industrial Health, was published and presented by the American Industrial Hygiene Association revealing that, contrary to popular belief, talcum powders were not entirely pure, but rather contained various fibrous minerals, including tremolite, anthophyllite, and chrysotile. This was not unexpected, as the study explains, because these types of fibers are often present in fibrous talc mineral deposits like those mined by Defendants for use in the Products. Available documents indicate that during the same year and in the years following, at least one company began testing store-bought talcum powders for asbestos content. Despite tests showing some commercial talcum powders contained asbestos, there is no evidence that these positive results or the brand names of contaminated products were communicated to any governmental agency, the media or the public. The study concluded that "[a]ll of the 22 talcum products analyzed have a . . . fiber content . . . averaging 19%. The fibrous material was predominantly talc but probably contained minor amounts of tremolite, anthophyllite, and chrysotile [asbestos-like fibers] as these are often present in fibrous talc mineral deposits . . . Unknown significant amounts of such materials in products that may be used without precautions may create an unsuspected problem." L. J. Cralley et al., Fibrous and Mineral Content of Cosmetic Talcum PRODUCT, 29 AM. INDUSTRIAL HYGIENE ASSOC. J. 350-354 (1968).

55. In 1971, the New York City Environmental Protection Administration Air Resources Board conducted a study of two "leading" brands of talcum powder using transmission electron microscopy ("TEM") and X-ray diffraction analysis ("XRD"), and found them to contain 5-25% tremolite and anthophyllite asbestos fibers.

56. A 1976 follow-up study of commercially available talcum products concluded that "[t]he presence in these products of asbestiform anthophyllite and tremolite, chrysotile, and quartz indicates the need for a regulatory standard for cosmetic talc . . . We also recommend that evaluation be made to determine the possible health hazards associated with the use of these products." Arthur Rohl, et al., Consumer talcums and powders: mineral and chemical characterization, 2 J. Tox. Envtl.. Health 255-284 (1976).

57. In 1981, Lockey in *Nonasbestos fibrous materials* (1981), reported that talc frequently exists in complex deposits containing quartz and asbestos, and that talc free from asbestos also contains talc in fibrous form.

58. Paoletti et al. *Evaluation by Electron Microscopy Techniques of Asbestos Contamination in Industrial, Cosmetic, and Pharmaceutical Talcs* (1983), analyzed talc powders from national and international markets in order to assess their fiber contents and the proportion of asbestos in the fibrous material. Analysis of talcum powder samples revealed that the powders contained fiber content up to 30% of total particles. About a half of the talc powders revealed the presence of asbestos.

59. In 1991, Alice Blount tested talcum powder mined from Vermont, including Johnson's Baby Powder, and found that the powder contained asbestos fibers and needles. Blount, A M. "Amphibole Content of Cosmetic and Pharmaceutical Talcs." *Environmental Health Perspectives* 94 (August 1991): 225–30; *See also* **Exhibit 19**, Deposition of Alice Blount (April 13, 2018) at 30:16-33:8; 47:15-25

60. On November 14, 2018, Drs. William Longo and Mark Rigler published a report detailing results from tests they performed on samples of the PRODUCTS provided by Johnson & Johnson dating from the 1960s to the early 2000s. 68% of the samples tested contained amphibole asbestos. The authors further found that 98% of the samples contained fibrous talc.

61. In 2019, the U.S. Food and Drug Administration (FDA) contracted AMA Analytical Services, Inc. to test samples of talc-containing cosmetics, including Johnson's Baby Powder. AMA identified chrysotile asbestos and talc fibers in a sample of Johnson's Baby Powder. As a result, Johnson & Johnson issued a recall of all bottles (approximately 33,000) from the sampled lot.

IV. Johnson & Johnson Concealed Evidence of Asbestos in the PRODUCTS Despite Knowing the Risks to Consumers

62. Beginning at least in the 1950s, Johnson & Johnson tested its talc for contaminant or co-minerals, including "asbestos" and "tremolite," because the company knew they are deleterious minerals that could be harmful to a person's health and thus should not be found in talc-based cosmetic products.

63. At all times relevant hereto Johnson & Johnson understood the dangers posed by asbestos exposure and that asbestos was a known contaminant of talc used in cosmetic and industrial products.

64. Internally, Johnson and Johnson historically defined "asbestos" as "the fibrous serpentine chrysotile and the fibrous forms of … anthophyllite, … tremolite, and actinolite." **Exhibit 20** (8/16/2018 Hopkins Dep. 174:24–175:23).

65. In addition to conducting its own internal tests described above, Johnson & Johnson hired testing laboratories, such as the Battelle Memorial Institute, McCrone Associates, the Colorado School of Mines Research Institute, and others to test for asbestos contamination (or co-mineralization) in the source talc ore used to manufacture Johnson's Baby Powder and Johnson & Johnson cosmetic products.[5]

[5] *See, e.g.*, **Exhibit 21** (4/12/1960 Battelle Memorial Institute report); **Exhibit 22** (10/15/1957 Battelle Memorial Institute report); **Exhibit 23** (5/23/1958 Battelle Memorial Institute report); **Exhibit 24** (7/31/1959 Battelle Memorial Institute report); **Exhibit 25** (8/31/1959 Battelle Memorial Institute report); **Exhibit 26** (9/15/1959 Battelle Memorial Institute report); **Exhibit**

66. All of these testing laboratories found asbestos minerals both in the source talc ore and Johnson & Johnson's cosmetic talc products.[6]

67. Tests performed by Johnson & Johnson and its consultants in the 1960s, 1970s, 1980s, and 1990s demonstrated that there was asbestos in the talc mined from Johnson & Johnson's Vermont mines.[7]

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27 (12/31/1959 Battelle Memorial Institute report); **Exhibit 28** (1/24/1968 Battelle Memorial Institute report); **Exhibit 29** (5/9/1958 Battelle Memorial Institute report); **Exhibit 30** (3/8/1960 Battelle Memorial Institute report); **Exhibit 31** (6/6/1961 Battelle Memorial Institute memo from W.L. Smith to W.H. Ashton summarizing observations of Smith Gouverneur, NY and Hammondsville, VT ore deposits, beneficiation products); **Exhibit 32** (8/25/1961 Battelle Memorial Institute memo from W.L. Smith to W.H. Ashton evaluating exploration work on Hammondsville talc deposit).

[6] *See, e.g.* **Exhibit 33** (4/14/1971, Colorado School of Mines Institute letter to Johnson & Johnson); **Exhibit 34** (10/27/1972, McCrone report); **Exhibit 35** (2/26/1973, Colorado School of Mines Institute to W. Ashton of Johnson & Johnson re: Mineralogical Exam of Five Talc Samples); **Exhibit 36** (6/6/1973, Johnson & Johnson memorandum); **Exhibit 37** (2/11/1974, McCrone to JJ Rolle); **Exhibit 38** (4/10/1974, McCrone to JJ Russell); **Exhibit 39** (4/24/1974, McCrone report); **Exhibit 40** (4/27/1973, Microscopic Exam of Johnson's Baby Powder); **Exhibit 41** (5/8/1974, McCrone report); **Exhibit 42** (7/8/1974, McCrone to J.J. Rolle); **Exhibit 43** (10/10/1974, McCrone to Windsor Minerals Inc.); **Exhibit 44** (12/9/1974, McCrone to Johnson & Johnson); **Exhibit 45** (7/1/1975, McCrone to Windsor Minerals Inc.); **Exhibit 46** (8/31/1976, Johnson & Johnson Memo Re: Vermont 66 Talc); **Exhibit 47** (9/11/1975, Stewart to V. Zeitz); **Exhibit 48** (11/5/1975, McCrone to Windsor Minerals Inc.); **Exhibit 49** (11/19/1975 McCrone to Windsor Minerals Inc.); **Exhibit 50** (7/5/1976, Colorado School of Mines Research Institute report); **Exhibit 51** (1/25/1977, F. Pooley to J.J. Rolle); **Exhibit 52** (4/1/1977, EMV Report to Johnson & Johnson); **Exhibit 53** (10/5/1978, McCrone to Windsor Minerals Inc.); **Exhibit 54** (2/9/1979, handwritten notes regarding conversation with Harold Cohen); **Exhibit 55** (11/6/1980, McCrone to Windsor Minerals Inc.); **Exhibit 56** (8/22/1985, McCrone to Windsor Minerals Inc.); **Exhibit 57** (4/29/1986, McCrone to Windsor Minerals Inc.); **Exhibit 58** (3/25/1992, Johnson & Johnson Interoffice Memo by Munro); **Exhibit 59** (12/4/1997, Bain Environmental Report); **Exhibit 60** (5/23/2002, Luzenac America Inc. (hereinafter "Luzenac") Technical Report); **Exhibit 61** (2/26/2004, Luzenac Product Certification Report); **Exhibit 62** (2/27/2004 Luzenac - Product Certification); **Exhibit 63** (3/4/2011, Summary of TEM Asbestos Results: Grade 66/96 USP Product Composites).

[7] *See* **Exhibit 64** (11/10/1971, Letter from A.M. Langer to G. Hildick-Smith); **Exhibit 65** (8/24/1972, Memo from W. Nashed to R.A. Fuller); **Exhibit 66** (9/25/1972, Memo from W.

68. Contaminants satisfying Johnson & Johnson's own definition of asbestos have been found in Johnson & Johnson talc, include "chrysotile," "tremolite," "anthophyllite," and/or "actinolite". *See, e.g.*, **Exhibit 73** (12/4/1970 Colorado School of Mines Institute testing results); **Exhibit 74** (6/30/1971 Colorado School of Mines Institute testing results); **Exhibit 75** (*Barden* Trial Ex. P3695-082-86: Summary chart of testing of Johnson's Baby Powder detecting asbestos and asbestos minerals).

69. The existence of laboratory tests finding asbestos in Johnson &Johnson cosmetic talc products and source talc used in those products was verified by Johnson & Johnson under cross examination in recent litigation. (**Exhibit 76**, Barden v. J&J, 8/14/19 at 148:17-21.)

70. As detailed in the following paragraphs, Johnson & Johnson executives acknowledged and communicated internally about the results of testing demonstrating the presence of asbestos in Johnson & Johnson's consumer talc products and the source ore used to make these products.

71. In 1972 for example, Johnson & Johnson's Al Goudie confirmed that McCrone found trace tremolite and that these findings are "not new." **Exhibit 77** (handwritten note from W. Nashed to Dr. Goudie).

72. In May 1973, Roger Miller, the President of Johnson & Johnson's mining company, Windsor Minerals, informed Dr. Dewitt Petterson of Johnson & Johnson that "the ore body

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Nashed to Fuller, Hildick-Smith, on Shower-to-Shower/Asbestos FDA Meeting 9/21/1972); **Exhibit 67** (6/12/1972, ES Laboratories Talc Analysis (Asbestos); **Exhibit 68** (12/13/1973, Memo from M.J.M. Oerlemans to J.H. Smids, H.L. Farlow, Re: Asbestos in Baby Powder); **Exhibit 69** (9/9/1975, Memo from G. Lee Re: A.M. Langer Analysis of Talcum Powder Products – Edinburgh Meeting); **Exhibit 70** (4/23/1998, Letter from A.M. Blount to R. Hatcher); **Exhibit 71** (Meeting with Dr. Langer on July 9 Concerning Analytical Analysis of Talc); **Exhibit 72** (University of Minnesota Investigation of Possible Asbestos Contaminations in Talc Samples).

contains actinolite." **Exhibit 78** (5/1/1973, Memo from R.N. Miller to Dr. Petterson). This talc ore body was actively used to produce Johnson & Johnson's cosmetic talc products.

73. One week later, Johnson & Johnson's William Ashton informed Dr. Petterson that "[t]he first showing of actinolite we know about is October 1972." **Exhibit 79** (5/8/1973, Memo from W. Ashton to D. Petterson).

74. In April 1969, Johnson & Johnson discussed the need to firm up the company's position on tremolite in talc because of potential dangers to human health and safety noted in the medical literature and by environmental health agencies. **Exhibit 80** (4/9/1969 Ashton to Hildick Smith - Alternate Domestic Talc Sources File No. 101).

75. Johnson & Johnson was concerned that the presence of tremolite in its cosmetic talc products, and thus, the resultant inhalation of talc with these needle-like crystalline structures, was related to the rising incidence of pulmonary diseases and cancer and increased the risk that the company would be drawn into litigation relating to these diseases and cancer. **Exhibit 81** (4/15/1969 Thompson to Ashton - Alternate Domestic Talc Sources File No. 101).

76. In July 1971, Johnson & Johnson reported a conversation with Dr. Clark Cooper, a professor at the School of Public Health at the University of California, Berkley, who expressed his concern that there is no place for asbestos in talc and any talc with asbestos should be removed from the market. **Exhibit 82** (7/30/1971 Hildick Smith to R.A. Fuller). According to Dr. Cooper, no level of asbestos in talc is acceptable for cosmetic use. *Id.*

77. Johnson & Johnson was aware of studies demonstrating that both talc and asbestos have been found in the tissue of women who never worked with asbestos or talc. **Exhibit 83** (2/19/2019 Nicholson Dep. 83:6-11).

78. Johnson & Johnson has known for many years that the talc used in Johnson's Baby Powder could be inhaled and reach deep into the lung. **Exhibit 13**, 11/28/2018 Musco Dep. 91:7-

19; *see also id.* at 130:1-21.

79. For decades, Johnson & Johnson has known about the dangers of talc powder inhalation during the normal and expected use of its talc-based cosmetic products, especially to babies. *Id.* at 111:2–112:15; *see also id.* at 116:11–119:18; **Exhibit 84** (5/27/2009 email from Nancy Musco).

V. Actions by Regulatory Bodies and Health Organizations

80. In the early 1970s, the FDA began an inquiry into whether to regulate and require warnings on consumer talcum powder products. The Johnson & Johnson Defendants and PCPC conspired and worked in concert to block efforts to label and warn consumers regarding the dangers associated with cosmetic talcum powder products, such as the PRODUCTS.

81. Contemporaneously, evidence began to emerge from testing conducted by various regulatory agencies revealing that asbestos was being found in food, beer and drugs, including intravenously injected medicines. In 1972, and later in 1973, the FDA filed notices of proposed rulemaking requiring talc used in food, food packing and drugs to be asbestos-free. These were some of the same grades of talc used and supplied by Defendants.

82. In 1987, the International Agency for Research on Cancer (IARC), the specialized cancer agency of the World Health Organization, published a paper in which it classified talc containing asbestiform fibers as a "Group 1" human carcinogen, finding sufficient evidence linking talc containing asbestiform fibers to the development of cancer in humans. *See* **Exhibit 85** (JNJ 000018820).

83. Upon information and belief, in or about 1990, the FDA asked manufacturers to voluntarily stop putting talc on surgical gloves because mounting scientific evidence showed that it caused adhesions in surgical patients, an indication of a foreign body reaction. On December 19, 2016, the FDA issued a ban on powdered surgical gloves, stating that "the risk of illness or

injury posted by powdered gloves is unreasonable and substantial." *See* **Exhibit 86** (FDA, 21 CFR Parts 878, 880, and 895 [Docket No. FDA–2015–N–5017] RIN 0910–AH02 Banned Devices; Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove).

84. In or about 1993, the United States National Toxicology Program published a study on the toxicity of non-asbestos form talc and found clear evidence of carcinogenic activity. Talc was found to be a carcinogen, with or without the presence of asbestos-like fibers. **Exhibit 87** (P-11 (JNJ000008945)).

85. On or about November 10, 1994, the Cancer Prevention Coalition mailed a letter to then Johnson & Johnson C.E.O., Ralph Larson, informing his company that studies as far back as 1960's ". . . show[ ] conclusively that the frequent use of talcum powder in the genital area pose[ ] a serious health risk of ovarian cancer." The letter cited a study by Dr. Bernard Harlow from Harvard Medical School confirming this fact and quoted a portion of the study where Dr. Harlow and his colleagues discouraged the use of talc in the female genital area. The letter further stated that 14,000 women per year die from ovarian cancer and that this type of cancer is very difficult to detect and has a low survival rate. The letter concluded by requesting that Johnson & Johnson withdraw talc products from the market because of the alternative of cornstarch powders, or at a minimum, place warning information on its talc-based body powders about the ovarian cancer risk they pose. *See* **Exhibit 88** (P-18 (JNJ 000016645)).

86. Upon information and belief, in or about 1996 and at the request of the FDA, the condom industry stopped dusting condoms with talc due to the growing health concerns. *See* **Exhibit 89** (P-19 (JNJTALC000365903)).

87. In or about 2006, the Canadian government, under The Hazardous Products Act and associated Controlled Products Regulations, classified talc as a "D2A," "very toxic," "cancer

causing" substance under its Workplace Hazardous Materials Information System (WHMIS). Asbestos is also classified as "D2A." *See* **Exhibit 90** (P-215 (IMERYS 255900)).

88. In 2008, the Cancer Prevention Coalition submitted a second "Petition Seeking a Cancer Warning on Cosmetic Talc Products" to the FDA. The first Citizen Petition had been filed on November 17, 1994. The second Petition requested that the FDA immediately require cosmetic talcum powder products to bear labels with a prominent warning that frequent talc application in the female genital area is responsible for major risks of ovarian cancer. The FDA response to the two Citizen Petitions was filed on April 1, 2014, twenty years after the first Petition was filed. *See* **Exhibit 91** (P-47 (JNJ 000542606)).

89. In February 2010, IARC published a paper whereby it classified perineal use of talc-based body powder as a "Group 2B" human carcinogen. *See* **Exhibit 92** (P-29 (JNJ000381975)). IARC, which is universally accepted as an international authority on determining the carcinogenicity of chemical substances and cancer issues, concluded that studies from around the world consistently found an increased risk of ovarian cancer in women who used talc in the perineal area. IARC found that between 16-52% of women in the world were using talc to dust their perineum and found an increased risk of ovarian cancer in women talc users ranging from 30-60%.

90. In 2012, IARC published another paper in which it concluded that asbestos exposure can cause ovarian cancer and listed asbestos as a "Group 1" human carcinogen. See **Exhibit 93** (P-817 (JNJ 000451296)).

91. Despite the IARC listing of talc and its constituents as a possible human carcinogens, documents show that industry, spearheaded by PCPC, continued their national, state and local promotional campaigns touting talc safety and recruiting scientists to publish articles that raised doubt about the link between perineal talc use and ovarian cancer. *See* **Exhibit 94** (P-78

(IMERYS-A_0005090)); **Exhibit 95** (P-92 (IMERYS-A_0001252)); **Exhibit 96** (P-348 (IMERYS 287251)); **Exhibit 97** (P-650 (IMERYS 288001)); and **Exhibit 98** (P-32 (IMERYS-A_0000127)).

92. In 2006, The Gilda Radner Familial Ovarian Cancer Registry, Roswell Park Center Institute, and the Department of Gynecologic Oncology at University of Vermont published a pamphlet entitled, "Myths & Facts about ovarian cancer: What you need to know." In this pamphlet, under "known" risk factors for ovarian cancer, it lists: "Use of Talc (Baby Powder) in the Genital Area." **Exhibit 99** (P-212).

93. In December 2018, Health Canada published a draft screening assessment on the safety of talc. The comprehensive scientific assessment included a Bradford Hill analysis of relevant epidemiological and animal studies. Health Canada concluded that there is a "statistically significant positive association between perineal exposure to talc and ovarian cancer" and "available data are indicative of a causal effect." **Exhibit 100** (JNJTALC001094046).

VI. Defendants' Actions in Response to the Evidence of Cancer Risk

94. Upon information and belief, since these early 1970s studies and the publications related to them, Defendants have been on notice of an association between talc exposure and ovarian cancer. Even before these studies specifically linking talcum powder to ovarian cancer, Defendants were aware of the human health hazards posed by talc as far back as the 1930s.

95. Johnson & Johnson was aware of the Henderson 1971 study and Tenovus data suggesting an association between talc and ovarian cancer. In an internal document, Defendants admit that this knowledge "puts them on notice" of the association. At or around this same time, Johnson & Johnson sent a donation to the Cardiff Scientific Society to obtain information concerning research being conducted by the Tenovus Institute, further proving they were on notice of the "talc and ovarian cancer problem." **Exhibit 101** (P-55 (JNJ 000026241)).

96. Johnson & Johnson acknowledged in internal company documents spanning decades of corporate history, its recognition and notice of the talc/ovarian cancer issue and that "if the results of any scientific studies show any question of safety of talc" use, Johnson & Johnson would "not hesitate to take it off the market." *See* **Exhibit 102** (P-660 (JNJ000488208)); **Exhibit 101** (P-55 (JNJ000026241)); and **Exhibit 103** (P-115 (JNJ000024495)). *See also* **Exhibit 104** (JNJ 000404425, 26), a November 2000 draft public relations statement for JNJ about switching to cornstarch only by December 1, 2000.

97. For decades, Johnson & Johnson has been repeatedly asked by consumers whether its cosmetic talc product ever contained any amount of asbestos. **Exhibit 13** (11/28/2018 Musco Dep. 40:17–41:12).

98. In response to these inquires, Johnson & Johnson has always assured consumers "Asbestos has never been found in Johnson's Baby Powder and it never will." *Id.* (11/28/2018 Musco Dep. 49:17–50:25, 51:17–52:10). Historically, when pressed, Johnson & Johnson always responded that there "is no evidence that Johnson's Baby Powder contained any amount of asbestos and there never was." *Id.* at 59:1-10.

99. Johnson & Johnson repeatedly told consumers and the public that "Baby Powder does not contain asbestos and never will. We test every single lot to ensure it." **Exhibit 105** (12/19/2018 Johnson & Johnson Ad).

100. Johnson's Baby Powder product label says it was the "Purest Protection" and it was advertised as "the best you can buy" and "the purest." **Exhibit 106** (P3695-265).

101. The intent of these representations to consumers has always been "to reassure them they could feel safe and comfortable using Johnson's Baby Powder because it does not contain asbestos" and to convey that in using Johnson's Baby Powder, there was "zero chance" of exposing their families to asbestos. **Exhibit 13** (11/28/2018 Musco Dep. 61:21–62:7); *see also* **Exhibit 1**

(2/15/2019 Musco Dep. 39:7–42:8).

102. The statements made to consumers by Johnson & Johnson, including that Johnson's Baby Powder does not contain asbestos and that there was "zero chance" consumers were exposing their families to asbestos, were false when they were made, and Johnson & Johnson knew they were false when they made those statements.

103. As a direct result of Johnson & Johnson's false representations that Johnson's Baby Powder never contained asbestos, millions of people, including babies, were unwittingly and needlessly exposed to asbestos. *See* **Exhibit 13** (11/28/2018 Musco Dep. 68:3–69:10).

104. Johnson & Johnson has never communicated to the public or federal government that it knew that its asbestos containing talc-based cosmetic products would be aerosolized and inhaled during normal use. *Id.* (11/28/2018 Musco Dep. 114:6-25).

105. Johnson & Johnson has never placed warnings on its talc-based powder products about the potential hazards presented by the product being aerosolized in normal application. *Id.* (11/28/18 Musco Dep. 188:2-9).

106. Johnson & Johnson never placed warnings on its talc-based powder products about the risk of asbestos exposure. *Id.* (11/28/18 Musco Dep. 188:13-17).

107. Johnson & Johnson purposely withheld from their spokespeople, whose job it was to communicate the "no evidence of asbestos" message, any reports indicating there was in fact evidence of asbestos in Johnson's Baby Powder. *Id.* (11/28/18 Musco Dep. 59:15–60:5, 61:16-20, 140:3-10, 215:13-18).

108. In 1973, PCPC created a talc subcommittee and the Scientific Advisory Committee to develop a testing methodology for detecting asbestos in talc. Initially, PCPC designated a group of its members to tests talc grades used in talcum powder utilizing the methodology proposed by the FDA in its notice of rulemaking. Six samples of talc used in commercially available talcum

powders, plus one talc sample purposely spiked with tremolite and chrysotile, were circulated among the members, including representatives of Defendants. Of the eight participating members, four found asbestos in every sample, three did not find asbestos in any sample (including the spiked sample), and one found asbestos only in the spiked sample. In conclusion, all members agreed that the best and most reliable method of detecting asbestos in talc is not optical microscopy, but rather TEM and electron diffraction. The same members, however, dispensed with this analytical method, claiming TEM and electron diffraction equipment was too expensive, despite Defendants then owning or having unfettered access to same.

109. Going forward, the difference between what Defendants knew diverged from what they were representing to the FDA. Defendants and others in the industry knew that there was no such thing as asbestos-free talc—only talc in which asbestos could not be detected using the adopted and most economical analytical methodology, XRD, which at the time could not accurately identify chrysotile asbestos in talc, nor detect tremolite asbestos contamination levels below 2-5%.

110. Defendants and third parties collectively met with and corresponded with PCPC and also met with the FDA to individually and collectively advocate for the use of "voluntary" XRD testing of miniscule portions of the tons of talc to be used in consumer products. Defendants' "voluntary" method—that was developed collectively by Defendants and advocated to the FDA in lieu of regulations requiring asbestos labeling or warnings on talcum powder products—was inadequate because levels of asbestos contamination in talc commonly fell below the detection limit of XRD. Defendants knew that the XRD detection limits were inadequate. Defendants also knew that asbestos contamination was not uniformly distributed, such that the miniscule amounts tested would not reveal the true level of contamination in talc products, such as those to which Plaintiffs were exposed.

111. In support of their voluntary XRD methodology, which was finally published in 1977, PCPC produced letters to the FDA written by its members, including Defendants, identifying tests conducted showing talcum powder products did not contain asbestos. PCPC, Defendants and other talc product producers, however, never informed the FDA of the hundreds of positive tests showing talc and talcum powders contained asbestos and other carcinogens. Defendants made and published representations claiming that their testing method was adequate, that they were ensuring that talcum powder products were safe, and that the talc reaching consumers was "safe," despite having substantial knowledge and evidence to the contrary. Defendants intentionally and knowingly did so to avoid FDA regulations that may have required them to place warnings regarding the asbestos content of their products, and thereby inform the public, including Plaintiffs, that talc-containing products contained asbestos.

112. The Defendants have represented to various news media outlets and the public at large that their products are "asbestos-free" when, in fact, their products did test positive for asbestos and those that did not were merely the result of inadequate and imprecise testing methods. "No asbestos detected" means something much different than "no asbestos," but due to Defendants' repeated conflation of the terms, the public has been led to erroneously believe talc products are safe.

113. Between 1970 and the 1990s, tests conducted by and on behalf of Defendants and the talc industry continued to show that talc and talcum powder products contained asbestos as well as other constituents such as fibrous talc, cadmium, cobalt, chromium, copper, iron, manganese, and nickel. None of these positive tests were ever produced or made known to any regulatory agency until late 2019, and only after knowledge of their existence became known in civil litigation.

114. Since at least 1979, Defendants have conducted a campaign to convince the public that their products are regulated by the FDA, their tests are conducted pursuant to FDA regulations, and that talcum powder products are, therefore, safe. Nothing could be further from the truth: the FDA has never been granted the regulatory authority by Congress to regulate cosmetics, including talcum powders.

115. Defendants, collectively by their agreement and conspiracy, controlled industry standards regarding the testing, manufacture, sale, distribution and use of talcum powder products, and controlled the level of knowledge and information available to the public, including Plaintiffs, regarding the hazards of exposure to carcinogens, including talc, asbestos, and fibrous talc. Defendants knowingly and intentionally released, published and disseminated invalid, inaccurate, outdated and misleading scientific data, literature containing misinformation and false statements regarding the health risks associated with the use of talc and talcum powder products, including those to which Plaintiffs were exposed.

116. Defendants, while cognizant of the aforementioned data, deliberately chose to ignore the health and safety issues raised in the data and embarked upon a plan of deception intended to deprive the public at large, including Plaintiffs, of alarming medical and scientific findings surrounding the safety of asbestos -containing talc and talcum powder products, many of which remained in their exclusive possession and under their exclusive control.

117. Defendants conspired and/or acted in concert with each other and/or with other entities through agreement and consciously parallel behavior: (a) to withhold from users of their products—and from persons who Defendants knew and should have known would be exposed thereto—information regarding the health risks of asbestos, talc, and other carcinogens contained in the PRODUCTS ; (b) to eliminate or prevent investigation into the health hazards of exposure to asbestos, talc and other carcinogens in the PRODUCTS; (c) to ensure that asbestos-containing

talc and talcum powder products became widely used in commerce, irrespective of the potential and actual risk of harm to the users and consumers from the asbestos, talc and other carcinogens therein; and (d) to falsely represent that talc and talcum powder products, including those of Defendants, were safe for use by consumers.

118. McCrone Associates, the laboratory selected by several talc producers—including Defendants—to analyze their products, was already using TEM for asbestos analysis. An article by McCrone and Stewart from 1974 describes the advantages of TEM for asbestos analysis and states that TEM "only recently installed in our laboratory will undoubtedly be the ideal instrument for the detection and identification of very fine asbestos fibers."

119. The PCPC "Method J4-1," published on October 7, 1976, states that TEM-SAED "offers greater sensitivity, but is not presented since it is unsuitable for normal quality control applications." The published J4-1 method did not rely on TEM, but on XRD with "the level of detection of amphibole by this method [being] 0.5% and above." PCPC met with and corresponded with Defendants and third parties to individually and collectively advocate to the FDA for the use of inadequate XRD testing on miniscule portions of the tons of talc obtained from the mining sources to be used in the consumer products, followed by tests by TEM when XRD was positive or suspicious.

120. This voluntary testing method was developed by PCPC and Defendants, and was advocated to the FDA by PCPC and Defendants in lieu of regulations requiring labeling and warnings on talcum powder products, even though PCPC and Defendants knew that the J4-1 method would not reveal the true level of asbestos in the talc that reached consumers. In fact, the first "round robin" tests, which analyzed a "PCPC Tremolite-Spiked Talc," resulted in 6 of 7 participating laboratories failing to detect the tremolite.

121. In other words, 84% of the industry's laboratories failed to detect asbestos in a sample known to contain tremolite asbestos while using PCPC's own J4-1 method. There is no evidence that the Defendants ever shared this remarkable failure with the FDA or the public.

122. The FDA, and ultimately Plaintiffs, directly and/or indirectly relied upon PCPC's false representations regarding the safety of cosmetic talc. In fact, a FDA letter dated January 11, 1979, states "In cooperation with scientists from industry, our scientists have been making progress in the development of such regulatory methods." The continuing lack of FDA awareness regarding PCPC's and Defendants' misrepresentations and concealment was obvious seven years later. In a response to a July 11, 1986 Citizen Petition requesting an asbestos warning label on cosmetic talc, the FDA stated that an "analytical methodology was sufficiently developed" to ensure that "such talc [is] free of fibrous amphibole…" PCPC's J4-1 method has continued for the past four decades to be the cosmetic talc industry's method for "ensuring" "asbestos-free" talc.

123. In 1990, Kremer and Millette published a TEM method for analysis of asbestos in talc with a theoretical detection limit of about 0.00005%. Despite such improvements in analytical techniques, the cosmetic talc industry continues, three decades later, to use and promote its antiquated and wholly inadequate J4-1 method.

124. On or about September 17, 1997, Johnson & Johnson's own toxicology consultant, Dr. Alfred Wehner, informed the company about false public statements being made by the Defendants regarding talc safety. **Exhibit 107** (P-20 (JNJ000040596)).

125. In response to safety issues related to talc and talc-based body powders, the Cosmetic Toiletry and Fragrance Association (CTFA), now known as Defendant PCPC, formed the Talc Interested Party Task Force (TIPTF). The TIPTF, which was originally formed in anticipation of litigation related safety issues, periodically convened, including in the 1970s and 1980s, to defend talc in response to safety concerns about talc. The TIPTF once again convened

in and around 1992 to combat the United States National Toxicology Program's study. Defendants Johnson & Johnson, Johnson & Johnson Consumer, Inc., and Luzenac – now known as Defendant Imerys Talc – were the primary actors and contributors to the TIPTF. *See* **Exhibit 108** (P-14 (JNJ000011704), **Exhibit 109** (P-83 (LUZ011963)); and **Exhibit 110** (02/18/2016 Mark Pollak Dep. Exhibit No. 2 Spreadsheet: Talc IP – Revenue Received; Date Initiated: 08/17/92).

126. The stated purpose of the TIPTF was to pool financial resources of these companies in an effort to collectively defend the use of talc and, specifically, talc-based body powders at all costs, in anticipation of future litigation, ensure self-regulation, and to prevent local, state or federal regulation of any type over this industry. Imerys and the Johnson & Johnson Defendants wielded considerable influence on TIPTF. TIPTF hired scientists to perform biased research regarding the safety of talc. Members of TIPTF, including Johnson & Johnson and Luzenac, edited reports of the scientists hired by this group before they were submitted to governmental agencies and/or released to the consuming public. Members of TIPTF knowingly released false information about the safety of talc to the consuming public, and used political and economic influence on local, state and federal regulatory bodies regarding talc. These activities were conducted by these companies and organizations, including the Johnson & Johnson Defendants, PCPC, and Luzenac, over the past four (4) decades in an effort to prevent regulation of talc and to create confusion to the consuming public about the true hazards of talc relative to cancer. *See* **Exhibit 108** (P-14 (JNJ000011704); **Exhibit 111** (P-13 (JNJTALC000249618)); **Exhibit 112** (P-122 (JNJ000021035)); **Exhibit 113** (P-66 (IMERYS-A_0006056)); **Exhibit 114** (P-90 (IMERYS 179104)); **Exhibit 98** (P-32 (IMERYS-A_0000127); **Exhibit 107** (P-20 (JNJ000040596)); **Exhibit 115** (P-12 (IMERYS-A_0021921); **Exhibit 116** (P-27 (JNJ000000636)); **Exhibit 117** (P-24 (JNJTALC000716846)); **Exhibit 118** (JNJTALC000224218).

127. At all times relevant, in anticipation of litigation and regulatory action, PCPC coordinated the defense of talc and talc-based body powder and acted as a mouthpiece for the members of the TIPTF, including the Johnson & Johnson Defendants and Imerys. PCPC, completely reliant on funding from cosmetic-industry companies, was motivated to defend talc and talc-based body powders to retain its members involved with these products and retain their revenues. Upon information and belief, and at all times relevant, PCPC's revenue has been predominantly generated through a dues system based in part on its members' annual sales. In addition, PCPC's salaries are nearly equivalent to the membership dues received, creating a direct pecuniary interest in defending the safety of talc, talc-based body powders and the PRODUCTS. *See* **Exhibit 119** (08/29/2018 Mark Pollak Dep. 104:11 – 105:18).

128. In and around the mid-1970s, the Cosmetic Ingredient Review ("CIR") was formed to give PCPC and the cosmetic industry more credibility for self-regulation. Since that time, CIR has reviewed the safety of ingredients used in the cosmetic and personal care products industry. Although Defendants have, at all relevant times, promoted CIR as an independent regulatory body, CIR is an organization within and wholly funded by PCPC. In fact, CIR shares the same office space with PCPC and its employees are paid by PCPC. *See* **Exhibit 120** (10/02/2018 Linda Loretz Dep. 828:23 – 829:7; 831:10 - 833:18; 834:20 - 835:2).

129. Over the years, CIR has reviewed thousands ingredients used in the cosmetics industry, but has only found 13 ingredients to be "unsafe for use in cosmetics." In contrast, CIR has deemed approximately 1,800 ingredients to be "safe as used." Additionally, the CIR Expert Panel annually holds two-day quarterly meetings to review substances. Over the course of these annual meetings, the panel is able to review about 500 ingredients per year. On average, only about 20 minutes is spent discussing the safety of each ingredient. See **Exhibit 121** (08/10/2017

Alan Andersen trial testimony, Echeverria v. JNJ, 3126:25 – 27), and **Exhibit 122** (08/11/2017 Alan Andersen trial testimony, Echeverria v. JNJ, 3291:10 – 3292:1).

130. Even though PCPC knew of the safety concerns surrounding talc and talc-based body powders for almost three decades, CIR did not begin to review talc until after the first lawsuit alleging a link between talc use and ovarian cancer was filed. Upon information and belief, during the CIR review process, Defendants, including PCPC, influenced the CIR scientists writing and performing the review and, ultimately, edited the reviews in a biased manner. Not surprisingly, when CIR published its final report in 2015, it found talc to be safe as used in cosmetics.

131. In or about 2006, Imerys Talc began placing a warning on the MSDS it provided to the Johnson & Johnson Defendants regarding the talc it sold to them to be used in the PRODUCTS. These MSDSs not only provided the warning information about the IARC classification, but also included warning information regarding "States Rights to Know" and warning information about the Canadian Government's "D2A" classification of talc. *See* **Exhibit 123** (IMERYS 081218).

132. Defendants knew of the adverse risks of using talc and talc-based body powders in the perineal area and ovarian cancer and had a duty to warn about the potential hazards associated with the use of the PRODUCTS. *See* **Exhibit 124** (P-341 (IMERYS 284935)).

133. Defendants, though having knowledge of the increased risk of ovarian cancer associated with genital use of talc-based body powder, nevertheless actively marketed the safety of the product to users and failed to inform customers and end users of the PRODUCTS of a known catastrophic health hazard associated with the use of the PRODUCTS, particularly when used by women in the perineal area. *See* **Exhibit 103** (P-115 (JNJ000024495)); **Exhibit 125** (P-374 (JNJ000093556)); **Exhibit 126** (P-81 (IMERYS-A_0001298)); and **Exhibit 18** (P-10 (JNJ000021093)).

134. In addition, Defendants procured and disseminated false, misleading, and biased information regarding the safety of talc, talc-based body powders and the PRODUCTS to the public, and used influence over federal, state and local governmental and regulatory bodies regarding talc and talc-based body powder. *See* **Exhibit 107** (P-20 (JNJ000040596)); **Exhibit 18** (P-10 (JNJ000021093)); and **Exhibit 127** (P-26 (IMERYS-A_0013094)).

135. In 2012, Johnson & Johnson sold Shower to Shower to Valeant Pharmaceuticals n/k/a Bausch Health Co. Inc. In 2019, Bausch Health announced that it had reformulated Shower to Shower to replace the talc in the product with cornstarch.

136. In 2016, Johnson & Johnson registered Baby Powder under the California Safe Cosmetics Act. This law was established to compel cosmetic manufacturers to register ingredients that are "known" or "suspected" carcinogens.

137. Defendants engaged in wrongful conduct and were negligent and created a dangerous and unreasonable risk of harm to others, including Plaintiffs, by mining, milling, processing, supplying, distributing, designing, manufacturing, and selling talcum powder products which contained asbestos and fibrous talc, which Defendants knew or should have known were dangerous and posed substantial risks of harm to others, including Plaintiffs.

138. Defendants have long employed and/or consulted with doctors, scientists, geologists, mineralogists, and toxicologists, and they have maintained extensive medical and scientific libraries and archives containing materials relating to the health hazards of talc and the presence of asbestos and asbestiform talc fibers in talc and talc deposits. Despite the wealth of knowledge, Defendants continued to mine, mill, process, supply, distribute, design, manufacture, and sell talcum powder products which Defendants knew or should have known were dangerous and posed substantial risks of harm to others, including Plaintiffs.

VII. Defendants Misrepresented or Concealed Information about Asbestos in the PRODUCTS from the Government and the Public

139. Since the early 1970's the FDA has repeatedly asked Johnson & Johnson whether it's talc-based products contained asbestos (**Exhibit 83** (2/19/2019 Nicholson Dep. 87:10-23) including, whether there was any evidence of any amount of asbestos in any Johnson & Johnson cosmetic talc product. *Id.* (2/19/19 Nicholson Dep. 88:20-24).

140. Johnson & Johnson's answer to the FDA's inquiries was always the same: there is no evidence of any amount of asbestos in any Johnson & Johnson cosmetic talc product. *Id.* (2/19/19 Nicholson Dep. 89:3-8).

141. While Johnson & Johnson's CEO has recently proclaimed that "we have always cooperated fully and openly with the FDA and other regulators and have given them full access to our talc testing results" the record is to the contrary. *See* **Exhibit 105** (12/19/2018 Johnson & Johnson Ad); *see also*, **Exhibit 128** (Alex Gorsky Video)[8] (Johnson & Johnson claims that it "has cooperated fully with the U.S. FDA and other global regulators providing them with all the information they requested over decades.").

142. In the early 1970s, independent scientists publicly reported finding asbestos in Johnson & Johnson talc products. *See* **Exhibit 64** (11/10/1971, Letter from A.M. Langer to G. Hildick-Smith), **Exhibit 69** (9/9/1975, Memo from G. Lee Re: A.M. Langer Analysis of Talcum Powder Products – Edinburgh Meeting), and **Exhibit 71** (Meeting with Dr. Langer on July 9 Concerning Analytical Analysis of Talc).

143. In response, Johnson & Johnson sought to discredit the independent scientists' results and hired consultants to refute the asbestos in talc findings. Some of Johnson & Johnson's

[8] A copy of the video of Alex Gorsky is available at: https://lanierlawfirm.sharefile.com/d-s8ae050614a248fb8

experts found asbestos when evaluating consumer talc products. These results were reported to Johnson & Johnson though the company never provided those results to the FDA. Johnson & Johnson's claim that it provided the FDA with its "entire background file on asbestos talc testing" related to the company's cosmetic talc products was untrue because it never provided the FDA with the test results it received that identified asbestos in its talc and cosmetic talc products. *See* **Exhibit 83** at 184:20–185:9 (2/19/19 Nicholson Deposition).

144. Johnson & Johnson did not tell the FDA that it possessed test results finding asbestos in the mine ore and the finished talc product, nor did it give those results to the FDA. **Exhibit 83** (2/19/2019 Nicholson Dep. 105:2-5).

145. Under cross-examination, Johnson & Johnson 's representative was forced to admit that despite claiming that it provided all testing to the FDA, Johnson & Johnson never provided any results of asbestos testing of its talc products or ore to the FDA for the Vermont mine after 1973. **Exhibit 129** (3/6/2019 Nicholson Dep. 293:12–294:19). These include tests in which fibers matching the Johnson & Johnson definition of asbestos were found. *Id.* at 349:6–353:23.

146. Since the early 1970s, Johnson & Johnson represented to the FDA that there was no tremolite or fibrous talc in its talc-based cosmetic products. **Exhibit 83** (2/19/2019 Nicholson Dep. 89:17–90:8); *see also* **Exhibit 130** (7/21/1971 J&J Memo to File: Special Talc Project No. 503 FDA Meeting).

147. Over the course of more than 4 decades, Johnson & Johnson represented to the FDA "over and over again" that there is not a single instance or report of asbestos – including chrysotile asbestos – in its products. **Exhibit 83** (2/19/2019 Nicholson Dep. 98:10-19).

148. Beginning in early 1970s, Johnson & Johnson represented to the FDA that its data "conclusively proves that Johnson's Baby Powder is free of asbestos." *Id.* (2/19/19 Nicholson Dep. 90:9-23); *see also* **Exhibit 131** (9/21/1971 Letter from W. Nashed to FDA Director R.

Schaffner) ("It is seen that the data conclusively proves that Johnson's Baby Powder is free of asbestos.").

149. Johnson & Johnson has represented to the FDA that "no amphibole materials have been detected" in the company's talc-based products. **Exhibit 83** (2/19/2019 Nicholson Dep. 99:2-21); *see also* **Exhibit 132** (3/15/1976 Letter from G. Lee re: Examination of Asbestos in Talc at 6).

150. When pressed, Johnson & Johnson went so far as to represent to the FDA that "there wasn't a shred of evidence to support the idea that either our Johnson's Baby Powder or Shower to Shower contained any chrysotile asbestos." **Exhibit 133** (12/13/1972 J&J Memo re: Meeting Nov. 1, 1972 with Dr. Schaffner – FDA); *see also* **Exhibit 83** (2/19/2019 Nicholson Dep. 90:24–91:18).

151. Johnson & Johnson knew that its standby consultant McCrone purposely omitted findings of asbestos in its talc-based products because it "would only tend to confuse the issue perhaps with the FDA" and offered that if Johnson & Johnson "decide[d] to use these reports with the FDA" to "please call us." **Exhibit 134** (10/12/1971 Letter from G. Grieger to A. Goudie); *see also* **Exhibit 129** (3/6/2019 Nicholson Dep. 327:14–328:21).

152. As a part of its testing and reporting protocol for Johnson & Johnson's talc-based products, McCrone would segregate any test results that were positive for the presence of asbestos in talc ore or cosmetic talc products from those that allegedly found "no quantifiable" asbestos. For instance, on April 29, 1986, under McCrone Project No. ME-2275 and Purchase Order WS-0503, McCrone authored two separate reports of test results for Windsor Minerals. The first was for 11 talc samples in which "no quantifiable" amounts of asbestiform were found. The second was for the three talc samples (noticeably extracted from the numbering sequence) in which traces of chrysotile were found. *Compare* **Exhibit 135** (Musco Dep. Ex. 8B, Tab 73) with **Exhibit 57**

(4/29/1986 *Edley* Samples).

153. As further explained in the paragraphs below, McCrone and Johnson & Johnson worked together to manipulate the asbestos testing results of Johnson & Johnson products done by outside laboratories and reported those manipulated findings to the FDA as negative results.

154. Although aware of McCrone reports to the contrary, Johnson & Johnson represented to the FDA that its consultant McCrone Associates never found asbestos in the talc ore that was used to make the PRODUCTS. **Exhibit 129** (3/6/2019 Nicholson Dep. 316:8-23); *see also id.* 326:20–327:2 (Johnson & Johnson cites McCrone tests to the FDA to support its position that there was "no evidence" of asbestos in the Shower to Shower product). This statement to the FDA was false.

155. In 1972, after Johnson & Johnson was notified that an FDA consultant found asbestos in the Johnson & Johnson talc products, Johnson & Johnson hired Professor Hutchinson from the Minnesota Space Center to privately test the products with the intention of refuting the FDA consultant's findings.

156. On September 20, 1972, in anticipation of a meeting with the FDA to discuss the asbestos test results, Johnson & Johnson executives arranged for its consultant, Ian Stewart of McCrone, to meet with Professor Hutchinson in the Chicago O'Hare airport. At that meeting, Professor Hutchinson informed Ian Stewart that he found "incontrovertible asbestos" in Johnson & Johnson's talc-based products (**Exhibit 136**) (handwritten notes by Professor Hutchinson). From there Mr. Stewart, on behalf of Johnson & Johnson, flew directly to Washington DC to meet with the FDA to discuss test results. Mr. Stewart never disclosed Dr. Hutchinson's findings of asbestos to the FDA. **Exhibit 137** (Ian Stewart Traveling Expense report).

157. Thereafter, Professor Hutchinson provided Johnson & Johnson with a formal report documenting his asbestos findings with photographs of the asbestos he found in the Johnson &

Johnson products. Johnson & Johnson produced excerpts of the report to the FDA, removing all references to Professor Hutchinson's "incontrovertible" findings of chrysotile asbestos**.** **Exhibit 129** (3/6/2019 Nicholson Dep. 339:20–341:9, 345:11-21).

158. Johnson & Johnson similarly never informed the FDA that it was aware of additional evidence demonstrating the presence of actinolite in Johnson's Baby Powder. *Id.* (3/6/19 Nicholson Dep. 325:4-15). For example, Johnson & Johnson did not submit a March 1974 test result from Professor Reynolds at Dartmouth College that "Actinolite is the dominant fiberform amphibole in the ore and talc product provided by Windsor Minerals." *Id*. (3/6/2019 Nicholson Dep. 346:24–347:2); *see also* **Exhibit 138** (JNJ 000266903)(3/1974 Memo re: Analysis of Talc Products and Ores for Asbestiform Amphiboles).

159. Instead, Johnson & Johnson submitted test results to the FDA from Dartmouth claiming that no amphiboles were found in the company's talc products. **Exhibit 83** (2/19/2019 Nicholson Dep. 158:10–159:1).

160. As part of its plan to mislead the FDA and falsely claim its talc ore and cosmetic talc products were free of any asbestos, Johnson & Johnson hired outside consultants to conduct tests of Johnson & Johnson talc products using test methods Johnson & Johnson knew would not detect asbestos at low levels. *Id*. (2/19/2019 Nicholson Dep. 196:19-24, 197:24–198:8).

161. Thereafter, Johnson & Johnson submitted test reports to the FDA as proof that its talc was asbestos free knowing that the methods used would not detect asbestos at low levels and, thus, were not reliable to rule out the presence of asbestos. **Exhibit 129** (3/6/19 Nicholson Dep. 255:23-256:4).

162. Instead of utilizing a method it knew was sensitive enough to find asbestos at low levels, Johnson & Johnson routinely used a testing method that was not sufficient to detect asbestos at those level and continued to submit the same false negative testing results to the FDA. This

method was known as J4-1.

163. The J4-1 testing method utilized "XRD" as the initial screen to determine if any further testing was necessary (with a level of detection of about 1%). **Exhibit 139** (CTFA Method J4-1 Part I & Part II). If the XRD test result was negative, no more testing would occur, and the sample would be reported as "none detected." This process virtually guaranteed that low levels of asbestos would never be found.

164. Johnson & Johnson similarly knew that XRD could not detect chrysotile at levels below two or three percent of the talc product and was also incapable of detecting low levels of tremolite. **Exhibit 83** (2/19/2019 Nicholson Dep. 196:19-198:8).

165. In the unlikely event an XRD test result was positive, Johnson & Johnson implemented a second step, polarized light microscopy ("PLM"), but instructed the PLM analyst not to count *all* of the fibers he or she would actually see under the microscope. **Exhibit 139**. Short fibers, below a defined size, recognized as carcinogenic, were excluded from any reporting. According to the J4-1 method, a fiber must have an aspect ratio (length to width) of 5:1 or greater, and both dispersion testing and fibrous morphology criteria must be satisfied before a particle can be identified as asbestiform. *Id*. and **Exhibit 140** (JNJNL61_000005032 (5/21/1995, Johnson & Johnson TM7024 TEM Analysis of Talc for Asbestiform Minerals)).

166. Johnson & Johnson knew and was advised of other methods of testing talc that were sensitive enough to detect the presence of small fibers of asbestos in its talc ore and/or cosmetic talc products and, thus, provide more accurate results than the testing it purposely utilized to increase the likelihood of negative results. One of those methods was the "pre-concentration" method. **Exhibit 141** (JNJ 000268037 (12/27/1973 Colorado School of Mines Research Institute report)); **Exhibit 36** (6/6/1973, Memo JNJAZ55_000005081 to Pooley from Rolle); **Exhibit 138** (JNJ000266903 (3/1974 Memo from R.C. Reynolds, Jr. to Windsor Minerals, Inc.)("a

concentration technique is mandatory because it brings the amphiboles into a reasonable concentration range for optical or other methods of analysis.")); **Exhibit 142** – JNJNL61_000007330 (Special Talc Studies Monthly Report, March, 1974 – Assay Methods for Asbestos Minerals in Talc); **Exhibit 143** (JNJ 000250919 (3/11/1974, Memo from J.P. Schelz to F.R. Rolle)); **Exhibit 144** (JNJNL61_000062964 (11/26/1974, Memo from J.P. Schelz to F.R. Rolle)) (collectively referred to as "concentration method").

167. Internal Johnson & Johnson memoranda prove the company considered "the limitation" of the concentration method "is that it may be too sensitive" and when used found traces of tremolite which the J&J testing methods would fail to expose**.** **Exhibit 145** (JNJAZ55_00001892 (5/16/1973, Memo from F.R. Rolle to T.H. Shelley)).

168. When Johnson & Johnson consultant, Dr. Fred Pooley, told Johnson & Johnson that the concentration method was being used in Great Britain, the method was rejected by Johnson & Johnson as not "in the worldwide company interest." **Exhibit 146** (JNJNL61_000062953 (2/18/1975 Johnson & Johnson Limited letter to Johnson & Johnson)).

169. Although many of Johnson & Johnson's consultants — including the Colorado Research School of Mines, Professor Pooley of Cardiff University, Professor Reynolds of Dartmouth College, and Professor Alice Blount of Rutgers University — found asbestos in Johnson & Johnson's talc-based cosmetic products using the pre-concentration method, the company did not provide any of those test results to the FDA. **Exhibit 83** (2/19/19 Nicholson Dep. 172:8-15).

170. Johnson & Johnson was also urged by its consultants to use TEM to test for asbestos as it was far more sensitive than the J4-1 method used by Johnson & Johnson. *See, e.g.*, **Exhibit 147** (JNJNL61_000006726 (5/18/1973, Message on from G.E. Heinze to W. Ashton *et al.* – Talc Symposium)); **Exhibit 148** (JNJ 000035507 (9/30/1992, Notes on Meeting with Professor

F. Pooley, Cardiff) ("TEM is the only suitable method for looking for fibers of biologically relevant dimensions in lungs, therefore it is logical to use the same technique for examining mineral products for biologically relevant fibers.")); **Exhibit 149** (Johnson & Johnson correspondence at FDA_FOIA_013573) ("I think we all recognize XRD, PCM, and PLM are simply not sensitive enough to provide complete assurance that the talc is free of detectable asbestos.").

171. Eventually, Johnson & Johnson began to use TEM as a testing method on a limited basis, but implemented a TEM reporting methodology designed to yield negative, rather than accurate results. In this regard, Johnson & Johnson intentionally limited the amount of each sample that was analyzed and required a high fiber count of the same mineral type before a positive result could be reported. Johnson & Johnson called its method TM7024.

172. According to Johnson & Johnson's TM7024 method, Johnson & Johnson would report the test results as negative and "not quantifiable" unless the scientist, who was directed to look only at approximately 10 percent of the material available to examine under the microscope, counted 5 or more asbestos fibers of the same variety. **Exhibit 140** (JNJNL_000005032 (5/21/1995, Johnson & Johnson TM7024 TEM Analysis of Talc for Asbestiform Minerals)). Thus, even if the examiner counted as many as 16 asbestos fibers (i.e. four fibers each of tremolite, actinolite, anthophyllite, and chrysotile) looking only at 10 % of the sample seen under the microscope, it would be reported as not finding asbestos or "not quantifiable."

173. Johnson & Johnson's position about the scientific propriety of its TM7024 testing protocol was and remains inconsistent with that of environmental and health agencies. The United States Environmental Protection Agency ("EPA") has refused to limit its concern to only the type of identifiable asbestos fibers Johnson & Johnson instructs its microscopists to count. **Exhibit 150** (4/20/2006 US EPA Region IX Response to the November 2005 R.J. Lee Group, Inc.).

174. To further reduce the likelihood of detecting asbestos in its cosmetic talc ore, Johnson & Johnson required J4-1 method testing on only a composite from every two silos of talc (each silo containing hundreds of tons of talc), TM7024 testing only quarterly from a composite of all siloed talc, and a monthly composite of float feed. **Exhibit 151** (JNJMX68_000002913 (10/4/1984, Memo from J.A. Molnar to B. Semple, on Evaluation Program for Talc)). As a result, the total amount of talcum powder Johnson & Johnson ever put under a microscope to test for asbestos was approximately 1/100 of a breath mint by weight. **Exhibit 152** (Testimony of Matthew Sanchez 1/29/20 134:19:135:20.).

175. Even though Johnson & Johnson tested miniscule amounts of product, and utilized methods specifically designed to yield negative results, asbestos was still found in Johnson & Johnson's cosmetic talc. **Exhibit 153** (chart of various testing results). Johnson & Johnson did not produce these asbestos-positive test results to the public until 2017.

176. In 1976, Johnson & Johnson rejected the FDA's request to provide the results of its respective periodic monitoring for asbestos. *See* **Exhibit 129** (3/6/19 Nicholson Dep at 255:17-256:6.)

177. Johnson & Johnson also submitted false and misleading statements through its trade association (CTFA).

178. In March of 1976, the CTFA told the FDA that all industry testing had shown all talcum powder products to be completely free of asbestos. **Exhibit 154** (JNJ000330157).

179. On March 15, 1976, George Lee, Director of Applied Research for Johnson & Johnson, wrote to the CTFA, with the "understanding that you would wish to submit this information to the FDA," that it was "erroneously reported in 1971 that our powder contained asbestos," that the Vermont talc is "highly purified," and that Johnson & Johnson confirms the "absence of asbestos materials in this talc." **Exhibit 132** WCD000009. This false information

was then transmitted by the CTFA to the FDA to "give assurance as to the freedom from contamination by asbestos form materials of cosmetic talc products." *See* **Exhibit 154** (JNJ000330157).

180. Two weeks later, on March 31, 1976, Johnson & Johnson met privately in Hillside, New Jersey. During this meeting, Defendants congratulated themselves on the "success" of the "presentations" to the FDA and agreed that they should not bind themselves to having to further update the FDA. See **Exhibit 155** (JNJ000299024).

181. On March 1, 1978, John Schelz, the Chairman of the CTFA Task Force On Round Robin Testing and then current employee of Johnson & Johnson, instructed the CTFA to "destroy your copy of the table" containing the results of the CTFA Task Force on Round Robin Testing of Consumer Talcum Products for Asbestiform Amphibole Minerals. **Exhibit 156** (JNJNL_000062534 (3/1/1978 correspondence from Johnson & Johnson to the CTFA)).

182. Although possessing test results indicating that the talc used in its talc-based products contained tremolite and chrysotile asbestos — reportable as asbestos under federal regulations — Johnson & Johnson represented to the National Toxicology Project (NTP) that there was never any evidence of asbestos in the talc used in Johnson's Baby Powder. **Exhibit 13** (11/28/18 Musco Dep. 200:12-25.)

183. Decades after asbestos was first reported, Johnson & Johnson continued to represent to the FDA that it had confirmed "the absence of asbestiform minerals" in its finished talc-based products. **Exhibit 157** (JNJ 000021285 (6/27/1995 Comments of CTFA in Response to a Citizens Petition at 7-8)).

184. As recent as 2016, Johnson & Johnson represented to the FDA that no asbestos structures have ever been found in its talc-based products in any testing anywhere in the world. **Exhibit 83** (2/19/2019 Nicholson Dep. 99:18–100:9); *see also* **Exhibit 158** (JNJ 000489313

(3/17/2016 J&J Response to FDA Request for Information on Talc at 12)). This statement made to the FDA was false.

185. In about 2013, while editing information for its website, Johnson & Johnson even acknowledged internally that it "cannot say our talc-based consumer products have always been asbestos free"[9] but made the representations anyhow. **Exhibit 159** (Draft 1 – Copy for SafetyandCareCommitment Website).

VIII. Johnson & Johnson Destroyed Relevant Evidence

186. Johnson & Johnson has had the duty to preserve evidence and documents relevant to foreseeable litigation, including the responsibility to suspend any document destruction policies beginning 1969, and certainly no later than 1971.

187. Since at least 1969, Johnson & Johnson was aware that it was foreseeable and likely that it would be sued in personal injury litigation alleging pulmonary injuries – including asbestos-related disease – attributable to Johnson & Johnson's talc-based products.

188. On April 15, 1969, Dr. T.M. Thompson, Medical Director for Johnson & Johnson, wrote to Mr. William H. Ashton, a Johnson & Johnson executive supervising the company's talc-based products, to advise him of danger relative to "inhalation" of the "spicule" or "needle-like" crystals of tremolite in Johnson & Johnson's talc. *See* **Exhibit 81** (JNJ000087991 (4/15/1969 Letter from T. Thompson to W. Ashton Re: Alternate Domestic Talc Sources) ("[S]ince pulmonary diseases, including inflammatory, fibroplastic and neoplastic types, appear to be on the increase, it would seem prudent to limit any possible content of tremolite in our powder formulations to an absolute minimum.")).

189. Although Dr. Thompson states that he was not aware of "any litigation involving

[9] *See* n. 2, *supra*.

either skin or lung penetration by our talc formulations," he cautioned Mr. Ashton that "since the usage of these products is so widespread, and the existence of pulmonary disease is increasing, it is not inconceivable that [Johnson & Johnson] could become **involved in litigation** in which pulmonary fibrosis or other changes might be rightfully or wrongfully attributed to inhalation of our powder formulations." *Id.* To that end, Dr. Thompson recommended that "someone in the Law Department should be consulted with regard to the defensibility of our position in the event that such a situation could ever arise." *Id.*; *see also* **Exhibit** 1 (2/15/2019 Musco Dep. 64:18–68:1).

190. Dr. Thompson further forewarned Mr. Ashton that the company could confront a situation where the company would be more or less compelled to remove its talc products "if it became known that our talc formulations contained any significant amount of Tremolite." *See* **Exhibit 81** (JNJ000087991 (4/15/1969 Letter from T. Thompson to W. Ashton Re: Alternate Domestic Talc Sources)).

191. Dr. Thompson's prediction of litigation came to fruition shortly thereafter. By the early 1970's, Johnson and Johnson was involved in litigating and planning its defense to personal injury cases related to its talc products.

192. Through the litigation process, Johnson & Johnson has been forced to identify documents from as early as 1971 (and from every year thereafter) relating to "ongoing," "pending," and "anticipated" litigation regarding Johnson's Baby Powder. **Exhibit 1** (2/15/2019 Musco Dep. 74:23–76:7, 93:3-16.).

193. Since at least 1971, Johnson & Johnson has known and recognized that information and documentation in the company's possession relevant to or produced in any particular talc-based lawsuit would be relevant to discovery in future talc-based cases. *Id.* (2/15/19 Musco Dep. 25:13-20.)

194. Johnson & Johnson has reported that during the 1970s alone, the company was sued

in talc-based cases in nearly each year of the decade. *Id.* (2/15/2019 Musco Dep. 81:25–82:18). Although Johnson & Johnson was legally obligated to retain the evidence, it does not know where the documents and evidence related to these cases are located or whether they even exist. *Id.* at 78:25-79:23; 80:6-81:24.

195. While the evidence from the cases is missing, documents listed on Johnson & Johnson's privilege log related to these cases date back to 1971. *Id*. at 93:3-16. The entries on the privilege log indicate that samples of talcum powder used in litigation existed at the time the litigation in the 1970s was pending, but those samples have not been produced. *Id*. at 93:17-94:16.

196. Although Johnson & Johnson, by its own admission, had an obligation to preserve evidence once litigation concerning the health effects of its talc products was foreseeable, it failed to do so. *Id.* (2/15/19 Musco) 278:24-280:23.

197. Johnson & Johnson knew and understood that evidence adduced in litigation concerning the health effects of its talc products would be material and relevant to other anticipated cases. *Id.* Yet Johnson & Johnson failed to preserve records from any of the lawsuits that alleged injuries as a result of Johnson's Baby Powder, talc, or asbestos, even though Johnson & Johnson knew that relevant and material documents existed and were in its possession.

198. Johnson & Johnson did not retain any samples of its talc ore or milled talc used in its talc-based cosmetic products, which it tested regularly, albeit insufficiently, for the presence of asbestos and asbestiform minerals at any time until 2017. *See* **Exhibit 160** (10/18/2018 Mittenthal Dep. 405:22-407:9; 424:2-425:7).

199. Although litigation was pending and anticipated, the samples chosen by Johnson & Johnson specifically to create test results were not retained under the company's evidence retention schedules and were not subject to any litigation-hold. *Id.* at 371:14-374:9; 384:8:387:4; 405:22-407:9.

200. Johnson & Johnson's failure to institute a litigation hold also made certain that the testing results were destroyed in accordance with its document retention policy. *Id*. at 405:22-407:1.

201. At all times relevant to this current lawsuit, Johnson & Johnson has been in complete control of all aspects of the domestic and foreign subsidiaries implicated in its talc, including, but not limited to, the testing of talc source ore mines and testing of finished Johnson's Baby Powder end-products. Johnson & Johnson knew, or should have known, that this material would be material in pending and anticipated cases alleging injury resulting from exposure to its talc products and, therefore, had a duty to preserve that testing evidence. Johnson & Johnson destroyed those testing results and discarded its samples of talc.

202. Johnson & Johnson failed to preserve talc samples maintained in its museum after 1982 when the museum was suspended, even though litigation was pending and anticipated at that time. **Exhibit 161** (7/12/2018 Gurowitz Dep. 157:24–159:17).

203. Johnson & Johnson did not instruct its consultants that repeatedly tested its talc ore and products to retain the samples tested, even though litigation was pending and anticipated. *See, e.g.*, **Exhibit 161** (7/12/2018 Gurowitz Dep. 158:12–159:16). Although Johnson & Johnson was acutely aware that it was McCrone's policy to dispose of samples 30 days after testing results were generated, it never instructed McCrone to retain any samples. *See, e.g.,* **Exhibit 162** (1/28/87 McCrone Letter at JNJTALC000387715).

204. Johnson & Johnson failed to retain all test results for the presence of asbestos and asbestiform minerals of the talc ore and milled talc used in its talc-based cosmetic products. **Exhibit 160** (10/18/18 Mittenthal Dep. 405:22-406:24).

205. Even after a litigation hold was finally issued in 2000, Johnson & Johnson failed to retain samples from its Worldwide Talc Survey. *See* **Exhibit 163** (JNJNL_000015761

(10/20/2000 Letter)).

206. In 2008, nearly ten years after the first litigation hold, Johnson & Johnson, when asked about retention time for "information related to the CTFA ingredient surveys" directed its employees to "PITCH them." *See* **Exhibit 164** (JNJ 000368489).

207. Any test results that Johnson & Johnson has not yet produced are presumed to be destroyed, as the disposal of these results were mandated by the company's evidence retention scheduled absent a litigation hold, which Johnson & Johnson never issued. *Id.*

208. In addition to final testing results, Johnson & Johnson failed to preserve any of the original scientific data underlying these results. Besides failing to retain the actual talc ore and milled talc samples, Johnson & Johnson did not retain photomicrographs, count sheets, or TEM grids and knowingly allowed for this evidence to be destroyed.

209. This missing scientific data is of utmost importance to the fair and proper vetting of Johnson & Johnson's defense. The limited underlying scientific data that still exists confirms that the reports of "no detectable" asbestos are belied by the underlying scientific data, which shows evidence of asbestos. *Compare* page 1 with pages 4 and 10 in **Exhibit 165**. There are countless similar non-detect letters with no underlying data.

210. Johnson & Johnson has not located the photomicrographs underlying the reported findings of asbestos minerals conducted by the University of Minnesota. **Exhibit 129** (3/6/2019 Nicholson Dep. 333:8-23).

211. In 1989, after facing litigation related to its talc-based products for nearly two decades and anticipating further litigation, Johnson & Johnson intentionally destroyed records relating to its Hammondsville, Vermont mining operations. **Exhibit 166** (JNJ 000240739 (11/23/1993 Denton to Ashton and Jones at p. 3)).

212. Johnson & Johnson has represented that "[i]f we had any reason to believe our talc

was unsafe, it would be off our shelves immediately." **Exhibit 105** (12/19/2018 Johnson & Johnson Ad).

213. Yet in the *Joly* case, Johnson & Johnson's Medical Services Department – including the company's Medical Director – recognized that the plaintiff, who had used Johnson's Baby Powder for years, had "scarring of lung tissue [that] was noted on x-ray." Furthermore, "Pulmonary function studies revealed very severe obstruction of the small airways. Consumer did not respond to bronchodilators. Talc crystals were identified in the consumer's sputum." *See* **Exhibit 1** (2/15/2019 Musco Dep. 155:18–158:25); *see also* **Exhibit 167** (JNJ 000058414 (5/10/1985 J&J Ingestions and Inhalations Memorandum)).

214. Besides this report, Johnson & Johnson has not located its records related to the *Joly* litigation even though Mr. George Lee, a Johnson & Johnson scientist, had a file on the case in his possession as late as July 1988. *See* **Exhibit 1** (2/15/2019 Musco Dep. 170:16–172:20). Yet, J&J's designated corporate representative concerning the history and substance of prior litigation was not supplied with a single piece of paper regarding the *Joly* case. *Id.* at 159:21-161:11.

215. Evidence indicates that Johnson & Johnson historically preserved no records whatsoever from the majority of cases in which it has been sued for causing talc related injuries.

216. For those cases where there is at least some documentation, Johnson & Johnson either lost or destroyed most of the material evidence related to historical litigation alleging asbestos-related disease from its talc-based products. *See e.g.*, **Exhibit 2** (3/8/2019 Musco Dep. 361:24-362:17) (missing *Westfall* photographs); **Exhibit 1** (2/15/2019 Musco Dep. 232:9-17) (missing *Edley* interrogatories); *id*. at 111:23–112:3 (no records from the *Cunningham* case); *id*. at 112:10-25) (no records from the *Kreppel* case); *id*. at 113:12–114:3) (no records from the *Lopez* case); *id*. at 114:19-22) (no records from the *Sheldon* case).

217. Despite being involved in countless cases dating back to 1971, Johnson & Johnson could only locate two sets of discovery responses for its corporate representative to review. *See id*. at 202:2-13).

218. Johnson & Johnson once maintained a paper file documenting all of its telephone conversations with the FDA related to its talc-based cosmetic products dating to the early 1970s. **Exhibit 83** (2/19/2019 Nicholson Dep. 48:9–15). The "FDA Call File" no longer exists. *Id.* at 113:25–114:19).

219. Johnson & Johnson once maintained toxicology information in boxes and binders. This toxicology information was never disclosed. *See* **Exhibit 13** (11/28/18 Musco Dep. 149:7–152:24).

220. In 1977, the Talc Task Force conducted "round robin" testing of talcum powder products manufactured by member companies.

221. John P. Schelz, a Johnson & Johnson employee and chair of the Talc Task Force, coordinated the testing and review of the testing data. *See* **Exhibit 168 (**JNJ 000250596).

222. Once the testing data was received, Schelz compiled the data in a table and assigned each sample a coded value. He then created a separate "code key" to interpret the coded value assigned to each sample.

223. He did not send the code key to any of the other companies. *See* **Exhibit 169** (JNJ 000265120).

224. Schelz sent the only other copy of the code key to Charles Haynes at PCPC with instructions to destroy the code key after Haynes called the companies to inform them of the results. *Id.*

225. Upon information and belief, both Schelz and Haynes destroyed the code keys to the "round robin" testing results. As a result, it's impossible to determine which products were tested. *Id.*

226. All companies involved in the "round robin" testing agreed to the process of destroying the code key.

227. From the 1950s to the 2000s, Defendant Johnson & Johnson (or outside laboratories, including RJ Lee and McCrone) tested samples of talc for asbestos content.

228. Upon information and belief, Defendant Johnson & Johnson failed to ensure the preservation of these samples, TEM grids, count sheets, photomicrographs, and other documents generated during the testing and, as a result, the samples, TEM grids, count sheets, photomicrographs, and other documents generated during the testing were destroyed.

229. Defendant Johnson & Johnson intentionally failed to preserve relevant documents generated in litigation in a number of cases filed against it between 1960s to the 1990s.

IX. Johnson & Johnson Lied to Courts and Litigants for More Than 40 Years

230. Johnson & Johnson knowingly and intentionally concealed relevant and discoverable evidence and made repeated false and misleading statements to plaintiffs, their counsel and the courts, ultimately leading to the dismissal of numerous cases. Upon dismissal of the cases, Johnson & Johnson destroyed all relevant records, including any discovery.

231. Despite being involved in litigation for decades, Johnson & Johnson never produced a single asbestos test in any case prior to 2017, even when specifically requested**.** **Exhibit 2** (3/8/2019 Musco Dep. 420:19–424:13); *see also* **Exhibit 1** (2/15/2019 Musco Dep. 262:2-13).

232. Many of the same Johnson & Johnson executives who were involved in discussions with the FDA about the company's talc-based cosmetic products were involved in defending

Johnson & Johnson in litigation alleging asbestos-related injuries from Johnson's Baby Powder and other talc-based cosmetic products. **Exhibit 2** (3/8/2019 Musco Dep. 381:25–383:23).

233. In litigation involving its talc products, Johnson & Johnson was repeatedly asked whether the talc used in any of its talc-based cosmetic products contained any amount of asbestos. **Exhibit 1** (2/15/19 Musco Dep. 37:1-20).

234. In defending against litigation, Johnson & Johnson represented to plaintiffs' counsel that "there was no evidence" of asbestos in the cosmetic talc used in Johnson's Baby Powder or Johnson & Johnson's Shower to Shower. **Exhibit 2** (3/8/19 Musco Dep. 400:12–401:15).

235. These representations exemplified Johnson & Johnson's pattern and practice in defending talc-injury litigation, which was to conceal all evidence of asbestos in its cosmetic talc products and represent that no such evidence ever existed. *Id.* (3/8/19 Musco Dep. 400:12–401:15).

236. In furtherance of this practice, Johnson & Johnson routinely provided sworn affidavits from company executives asserting that there was no evidence of asbestos in the talc used for Johnson & Johnson cosmetic products. *Id.* (3/8/19 Musco Dep. 415:8–417:7)

237. Johnson & Johnson similarly repeatedly certified answers to interrogatories in asbestos-injury cases stating that there was never any evidence of asbestos in any Johnson & Johnson cosmetic talc product. **Exhibit 1** (2/15/2019 Musco Dep. 139:8-22).

A. *Westfall v. Whittaker Clark & Daniels*, et al., No. 79-0269 (D.R.I.)

238. In 1979, David Howard Westfall filed an asbestos death lawsuit in the United States District Court for the District of Rhode Island captioned *Westfall v. Whittaker Clark & Daniels, et al.*, C.A. No. 79-0269 (hereinafter referred to as "*Westfall*"), arising out of exposure to asbestos-containing talc products sourced from the Vermont mines.

239. As a result of its active involvement with the *Westfall* case, Johnson & Johnson knew that scientists involved in testing the talc clearly testified that the talc originating from the Johnson mine contained asbestos. The Johnson mine was once owned by Johnson & Johnson.

B. *Gambino v. Johnson & Johnson Baby Products Co.*, No. L-064200-83 (N.J. Super.)

240. In 1983, Johnson & Johnson was named as a defendant in another product liabiliy action captioned *Gambino v. Johnson & Johnson Baby Products Company,* Docket No. L-064200-83, Superior Court of New Jersey, Law Division, Middlesex County (hereinafter "*Gambino*").

241. In *Gambino,* the plaintiff alleged that his talcosis diagnosis was a direct result of exposure to and use of Johnson's Baby Powder. Although documents were once in the control of Johnson & Johnson's Legal department, no evidence from the case exists with the exception of the complaint and answers to one set of interrogatories. *See* **Exhibit 13** (11/28/18 Musco Dep. 89:2–90:1); **Exhibit 1** (2/15/19 Musco Dep. 105:16–107:5).

242. Johnson & Johnson never issued a litigation hold during the *Gambino* proceedings and presumably any other case involving talc used in its cosmetic talc products in the 20th century. *See* **Exhibit 170** (10/19/18 Mittenthal Dep. 478:1-481:9).

C. *Yuhas v. Windsor Minerals, Inc., et al.*, No. MID-L-029706-84 (N.J. Super.); *Edley v. Windsor Minerals Inc., et al.*, No. MID-L-075913-86 (N.J. Super.).

243. In 1986, the *Edley* case was filed in Middlesex County New Jersey. Mr. Edley alleged he developed asbestosis as a result of working with talc from Johnson & Johnson's Vermont talc mine.

244. In order to get Mr. Edley to dismiss his case, the President of Windsor Minerals, Roger Miller, signed an affidavit under oath on July 13, 1987 representing — "All of the talc mined by Windsor Minerals, Inc., whether it is ultimately sold to industrial users or used in Johnson's Baby Powder, is sampled and tested for the presence of asbestos. ***No evidence of the***

presence of asbestos in Windsor Minerals' product ***has ever been revealed*** by this testing. Attached as Exhibit 'A' is a true copy of a recent report of that testing." **Exhibit 171** (Affidavit of Roger Miller, *Edley v. Windsor Minerals, Inc.*, No. MID-L-075913-86 (N.J. Super. Ct. Middlesex Cnty.)) (emphasis added).

245. Roger Miller's affidavit attached an Exhibit "A", was the report of a 1987 assay by McCrone that found "no quantifiable amounts of asbestiform minerals" in Windsor talc samples. *Id*.

246. Not only did Johnson & Johnson fail to disclose all of the prior asbestos findings, it failed to disclose a similar assay from McCrone done a few months earlier that "resulted in the detection of trace amounts of chrysotile asbestos" in Windsor talc samples from the same source.

247. In urging the *Edley* plaintiff to agree to dismiss his case, Johnson & Johnson cited to a similar case named *Yuhas* where the plaintiff had previously agreed to dismiss his case based upon a similar false affidavit. *See* **Exhibit 172** (Windsor Ans. to *Yuhas* Compl. and Stip. of Dismissal).

248. In a recent trial in the same courthouse, Johnson & Johnson's corporate representative was forced to admit under oath that the representations made in Miller's affidavit were false and perjurious. *See* **Exhibit 173** (7/23/2019 *Barden* Hopkins Trial Tr. 189:1–195:4).

249. In reliance upon the fraudulent affidavits and affirmations, Mr. Edley voluntarily dismissed his case as Yuhas did before him. *See, e.g.*, **Exhibit 174** (Stipulation of Dismissal, R.B. Grayzel); **Exhibit 172** (*Yuhas* dismissal).

D. Countless fraudulent dismissals followed in the 1980s and 1990s.

250. When Johnson & Johnson entered into negotiations with Cyprus to sell its wholly-owned subsidiary, Windsor Minerals Inc., the parties included an indemnification provision for then-current asbestos-in-talc litigation, including claims for asbestosis arising from talc exposure.

See **Exhibit 175** (Cyprus Agreement of Transfer).

251. The agreement provided the details of numerous claims and lawsuits regarding injuries allegedly due to asbestos and talc. *Id.*

252. "Exhibit I" to Indemnification agreement establishes that Johnson & Johnson was aware of susbtantial pending and probable asbestos-in-talc litigation involving Windsor Minerals Inc., including the cases of 982 plaintiffs, all of whom suffered from asbestos-related diseases and attributed their injuries to exposure to asbestos and asbestos-containing talc. *Id*.

253. While scant evidence exists from the approximate 1000 dismissed cases involving Windsor Minerals, discovery has disclosed false sworn discovery responses as well as affidavits similar to that used to secure dismissals in the *Edley* and *Yuhas* cases executed by Roger Miller and other Johnson & Johnson executives.

254. On July 8, 1988, a year after executing his affidavit in the *Edley* case, Roger Miller executed another sworn affidavit attesting — "All of the talc mined by Windsor Minerals, Inc. has been regularly sampled and tested for the presence of asbestos. ***No evidence of the presence of asbestos*** in Windsor Mineral, Inc.'s product ***has ever been revealed*** by this testing." **Exhibit 176** (Affidavit of Roger Miller, *Andonian v. A.C. & S, Inc.*, No. ACV-88-6-1731 (Summit Cnty. Ct. Comm. Pls.)) (emphasis added).

255. **On the same date in a different case,** Roger Miller again swore — "All of the talc mined by Windsor Minerals, Inc. has been regularly sampled and tested for the presence of asbestos. ***No evidence of the presence of asbestos*** in Windsor Mineral, Inc.'s [product] ***has ever been revealed*** by this testing." **Exhibit 177** Affidavit of Roger Miller, *Miller v. A.C. & S, Inc.*, No. ACV884-1087 (Summit Cnty. Ct. Comm. Pls.) (emphasis added).

256. On May 8, 1989, Johnson & Johnson executive William Ashton, often referred to as "Mr. Talc", averred under oath in Somerset County, New Jersey that "From the 1940s through

the 1980s, talc mined in Vermont … has been considered to be talc free from contamination by asbestos." **Exhibit 178** (Affidavit of William Ashton (Somerset Cnty., N.J.)).

E. *Ritter v. Cyprus, et al.*, No. 93-5121-CV-8 (W.D. Mo.)

257. In 1993, Johnson & Johnson was named as a defendant in the matter of *Ritter v. Cyprus et al.* (hereinafter "*Ritter*"), related to injuries caused by Johnson & Johnson's talc products. *See* **Exhibit 179** (10/17/1994 Luzenac America Inc. letter to Johnson & Johnson).

258. Discussions between Johnson & Johnson and its talc supplier, Cyprus, regarding the *Ritter* litigation confirmed that Johnson & Johnson and its talc supplier destroyed all samples of talc tested for the presence of asbestos, including the samples tested by Johnson & Johnson's retained laboratory, McCrone Associates. **Exhibit 170** (10/19/2018 Mittenhal Depo. 496:21:14–504:1).

259. Despite being properly requested, the related documents, information, and samples, was never identified, disclosed, or produced in litigation.

F. *Selby v. Johnson & Johnson, et al.*, No. 670577 (Cal. Sup. Ct.).

260. In 1994, Marlene Selby and Lowell Wayne Selby filed a lawsuit in the Superior Court of California, County of San Diego, captioned *Selby v. Johnson & Johnson, et al.* (hereinafter "*Selby*"), alleging that Mrs. Selby's talcosis was caused as a direct result of exposure to Johnson's Baby Powder.

261. In *Selby*, Johnson & Johnson made the false represention in answers to interrogatries that its talc products never contained asbestos. *See* **Exhibit 180** (4/20/1994 Johnson & Johnson's Supplemental Responses to Plaintiffs' Special Interrogatories in *Selby*).

G. *Coker v. Johnson & Johnson, et al.*, No. D-157,746 (Tex. 136th Judicial Dist. Ct.).

262. In September 1997, Darlene Coker and her husband, Roy Coker, filed suit against Johnson & Johnson and others in the 136th Judicial District Court of Jefferson County, Texas

("*Coker*").

263. On May 6, 1998, Johnson & Johnson served its responses to plaintiffs' interrogatories and requests for production ("*Coker* discovery responses"). **Exhibit 181**.

264. In Johnson & Johnson's "Preliminary Statement" in the *Coker* discovery responses, Johnson & Johnson, stated in pertinent part:

> Johnson & Johnson Consumer Companies, Inc. (hereinafter Johnson & Johnson) states that in the preparation of its responses to plaintiffs requests and interrogatories, it has made, and continues to make, a concerted good faith effort to collect all of the requested information or documents from Johnson & Johnson as well as any relevant predecessors and vendors.
>
> ***
>
> As for its responses to interrogatories, Johnson & Johnson state that when the requested information is readily available from documents, the documents will be produced as noted in individual interrogatory responses.
>
> ***
>
> In response to requests for documents and interrogatories, Johnson & Johnson will produce information relevant to talc or baby powder.

Id.

265. In the *Coker* discovery responses, Johnson & Johnson concealed and refused to produce documents from any analyses of Johnson's Baby Powder for fibrous material or for asbestiform material, objecting that such requests for documents constituted a "fishing expedition," even though Johnson & Johnson knew that relevant and material documents showing the asbestos content of Johnson & Johnson's cosmetic talc products existed. *Id.*

266. Johnson & Johnson concealed and refused to produce in response to plaintiffs' discovery requests, any geological surveys or documents regarding the source mines for Johnson & Johnson's talc products despite knowingly possessing documents relating to the Vermont mines, which were owned and operated by Johnson & Johnson's wholly-owned subsidiary prior to 1989.

267. Johnson & Johnson concealed and refused to produce in response to plaintiffs' discovery requests in *Coker* any documents evidencing or relating to tests, studies, investigations, and analyses of Johnson's Baby Powder for the presence of asbestos at the request of, or by, Johnson & Johnson, members of the CTFA, Johnson & Johnson's talc suppliers, the federal government, McCrone, E.S. Laboratories, Colorado School of Mines Research Institute, Bain Environmental, or other outside laboratories in the 1950, 1960s, or 1970s, despite Johnson & Johnson's knowledge that relevant and material documents existed and were in its possession. *See* **Exhibit 181** (J&J interrogatory responses).

268. Johnson & Johnson concealed and refused to turn over these documents despite knowing that it had an obligation to turn over what was requested. *See* **Exhibit 1** (2/15/19 Musco Dep. 279:11-17).

269. In response to plaintiffs' questioning regarding whether Colorado School of Mines Research Institute or McCrone "found the presence of asbestos or asbestiform minerals" in its testing of Johnson & Johnson talcum products, Johnson & Johnson objected, asserting that such a request violated the Texas Rules of Civil Procedure as it requested proprietary and trade secret information and required each witness "to speculate and provide an expert opinion that [the] witness is not qualified to express." **Exhibit 2** (3/8/2019 Musco Dep. 402:4–405:21).

270. Notably, the Colorado School of Mines Research Institute, who had been retained by Johnson & Johnson since the 1950s, repeatedly and consistently detected the presence of asbestos in Johnson & Johnson's talc sources, yet Johnson & Johnson failed to disclose this information or produce said testing results during the *Coker* litigation.

271. Similarly, McCrone Associates, also retained by Johnson & Johnson since the 1970s, repeatedly and consistently detected the presence of asbestos in Johnson & Johnson's talc sources, yet Johnson & Johnson failed to disclose this information or produce said testing results

during the *Coker* litigation.

272. Finally, Johnson & Johnson was aware that E.S. Laboratories, who had also been retained by Johnson & Johnson, reported a finding of 1% chrysotile asbestos in Italian talc A.G.T. 1615, the same talc source used in Johnson's Baby Powder and Shower to Shower, but Johnson & Johnson never disclosed this information during the *Coker* litigation.

273. Instead, while defending against the plaintiffs' claim, Johnson & Johnson represented to the plaintiffs' counsel that "there was no evidence" of asbestos in the cosmetic talc used in Johnson's Baby Powder and Johnson & Johnson's Shower to Shower. **Exhibit 2** (3/8/2019 Musco Dep. 400:12–401:15).

274. In defending the *Coker* case, Johnson & Johnson contacted Dr. Alice M. Blount, Ph.D., a Rutgers University professor and researcher who had studied the asbestos content of various cosmetic talc products about serving as the company's consultant. Subsequently, on April 23, 1998, Dr. Blount advised Johnson & Johnson's counsel that the "Sample I" referred to in her 1991 paper "Amphibole Content of Cosmetic and Pharmaceutical Talcs" was a sample from Johnson & Johnson's Vermont mines that was found to have contained asbestos. **Exhibit 70** JNJ 000064241 (4/23/1998 correspondence from Dr. Blount). In this letter, Dr. Blount states "[a]s I told you, I believe that Johnson & Johnson's Vermont talc contains trace amounts of asbestos…" *Id.*

275. Sample I in Dr. Blount's study was found to contain asbestos at levels that would not have been identified using the industry-created procedure, the J4-1 method, for which Johnson & Johnson had advocated, used in-house, and required its outside laboratories to use. Sample I was a sample of Johnson's Baby Powder, though the identity of its manufacturer was not disclosed in Blount's article. Johnson & Johnson concealed this information and never disclosed it to the plaintiffs during litigation. *Id.*

276. Johnson & Johnson knew that Dr. Blount had found asbestos in Johnson's Baby Powder but concealed this fact and never informed the plaintiffs or their counsel of this fact.

H. *Krushinski v. Johnson & Johnson Baby Products Co.*, Docket No. MID-L-9389-99 (N.J. Super.)

277. In *Krushinski v. Johnson & Johnson Baby Products Co.*, Docket No. MID-L-9389-99, Superior Court of New Jersey, Law Division, Middlesex County (hereinafter "*Krushinski*") Johnson & Johnson again objected to producing scientific testing to determine whether there are any health risks in Johnson's Baby Powder as confidential, proprietary trade secrets. **Exhibit 182** (*Krushinski* Interrogatories at 3).

278. In *Krushinski*, Johnson & Johnson also again certified interrogatories swearing that "talc used in the manufacture of Johnson's Baby Powder **never contained asbestos in any form, or tremolite**." *Id.* at 7 (emphasis added); *see also* **Exhibit 1** (2/15/19 Musco Dep. 123:18–124:1); **Exhibit 13** (11/28/2018 Musco Dep. 90:2-14).

279. Johnson & Johnson has since been forced to admit that these interrogatories, which were answered in conjunction with the company's lawyers, are false. *See* **Exhibit 4** (7/22/2019 *Barden* Hopkins Trial Tr. 139:14–140:15).

280. Johnson & Johnson also admitted that it cannot be sure that the information that was available to it during the pendency of the *Gambino* case was available to it years later in the *Krushinski* case. **Exhibit 13** (11/28/18 Musco Dep. 88:5-23).

281. Yet, Johnson & Johnson knew there was tremolite in Johnson's Baby Powder when responding to the *Krushinski* discovery requests. **Exhibit 129** (3/6/2019 Nicholson Dep. 319:21–320:2).

282. In making representations in asbestos-injury litigation, Johnson & Johnson knew there was a difference between representing that there is "no evidence" of asbestos contamination and acknowledging that evidence exists, but claiming it is unreliable. Despite this knowledge,

Johnson & Johnson chose to represent that there was "no evidence" of asbestos contamination. **Exhibit 1** (2/15/2019 Musco Dep. 173:10-21).

283. In certifying answers to interrogatories, it was Johnson & Johnson's pattern and practice that its representative signing the responses never review a single document. **Exhibit 13** (11/28/2018 Musco Dep. 77:6-11); *see also id.* at 21:1-15.

284. In certifying answers to interrogatories, it was Johnson & Johnson's pattern and practice that its representative signing the responses never independently verify whether the information supplied was truthful and complete. *Id.* (11/28/2018 Musco Dep. 135:22–136:9).

I. *Durham v. Metropolitan Life Ins. Co.*, No. 05C-07-136 ASB (Del. Sup. Ct. New Castle Cnty.)

285. On September 19, 2006, Johnson & Johnson Executive John Hopkins executed another fraudulent affidavit swearing:

a. "The conclusion of the Audits was that for both of the Italian and Vermont mines, there was ***zero evidence*** of asbestos in the geology and mineralogy of the mines."

b. "For the talc sources in use in the United States over the period 1955-2002, there has ***never*** been an instance of asbestos contamination."

c. "***No evidence*** of asbestos in the mineralogy and geology in the talc mines supplying Johnson & Johnson in the United States"

d. "***No evidence*** of asbestos contamination in each production batch sampling as certified by the suppliers, from the period 1975 – date."

e. "It may be concluded that there has ***never*** been asbestos contamination of the talc used by Johnson & Johnson in the United States from the period in question, 1955-2002." **Exhibit 183**.

J. *Payan v. CBS Corp., et al.*, Caso No. BC 608412 (Cal. Sup. Ct., Los Angeles Cnty.)

286. On July 7, 2016, Dr. John Hopkins executed another fraudulent affidavit swearing **(Exhibit 184**) (7/7/2016 Affidavit of John Hopkins):

a. "***Confirmation of the absence of asbestos*** on a historical basis has been reported in a Johnson & Johnson internal report from 1966 that summarized the results of 13 samples of talc from the Company Museum and dating from the period 1910-1964."

b. "The conclusion of the Audit was ***that there was zero evidence of asbestos*** in the geology and mineralogy of the Italian mine."

c. "Based on the absence of asbestos contamination in historical talc samples; an in-house raw material specification requirement dating from at least 1949, for absence of asbestos in talc; no evidence of asbestos in the mineralogy and geology in the talc mines supplying Johnson & Johnson in the United States; and no evidence of asbestos contamination in each production batch sampling as certified by the suppliers, from the period of 1975 to the present, it is my expert opinion that Johnson & Johnson baby powder … was not contaminated with asbestos."

X. Federal Standards and Requirements

287. Certain federal standards and requirements apply to both talc as a cosmetic ingredient and talc-based body powder products. *See* **Exhibit 185** (P-324 (21 C.F.R. 740.1)).

288. At all relevant times, Defendants had the obligation to comply with federal standards and regulations in the manufacture, design, marketing, branding, labeling, distribution, and sale of the PRODUCTS.

289. Defendants, each individually, *in solido,* and/or jointly, violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.*, and regulations promulgated thereunder.

290. Defendants have or may have failed to comply with federal standards and requirements governing the manufacture, design, marketing, branding and sale of the PRODUCTS

including, but not limited to, the following violations of sections and subsections of the United States Code and the Code of Federal Regulations:

a. The PRODUCTS are adulterated pursuant in violation of 21 U.S.C. § 361 because, among other things, they contain a poisonous or deleterious substance which may render them injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.

b. The PRODUCTS are misbranded in violation of 21 U.S.C. § 362 because, among other things, their labeling is false or misleading.

c. The PRODUCTS are misbranded in violation 21 U.S.C. § 362 because words, statements or other information required by or under authority of 21 U.S.C. § 362 are not prominently placed thereon with such conspicuousness and in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

d. The PRODUCTS are misbranded in violation of 21 C.F.R. § 701.1 because they contain false or misleading representations that they are safe for daily application to all parts of the female body.

e. The PRODUCTS do not bear a warning statement, in violation of 21 C.F.R. § 740.1, to prevent a health hazard that may be associated with the PRODUCTS, namely that the PRODUCTS may cause ovarian cancer or a heightened risk of ovarian cancer when applied to the perineal area.

f. The PRODUCTS do not prominently and conspicuously bear a warning statement, in violation of 21 C.F.R. § 740.2, as to the risk of ovarian cancer caused by use of the PRODUCTS when applied to the perineal area, in such terms and design that

it is likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

g. The PRODUCTS, in violation of 21 C.F.R. § 740.10, do not conspicuously state on their principal display panel that the safety of the PRODUCTS have not been determined and/or that the safety of the PRODUCTS' principal ingredients have not been determined.

COUNT I - STRICT LIABILITY-FAILURE TO WARN
(Against Imerys Talc)

291. Plaintiffs incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the individual Plaintiffs' resident State.

292. Imerys Talc is liable under a theory of strict products liability as set forth in §402A of the Restatement of Torts (Second).

293. At all relevant times, Imerys Talc mined and sold talc to the Johnson & Johnson Defendants with full knowledge that the Johnson & Johnson Defendants were then packaging the talc and selling the talc to consumers as the PRODUCTS and that consumers of the PRODUCTS were using it to powder their perineal regions.

294. At all relevant times, by mining, refining, screening and testing talc, and supplying that talc to the Johnson & Johnson Defendants for use in the PRODUCTS, Imerys Talc was knowingly an integral part of the overall manufacture, design and production of the PRODUCTS, and the PRODUCTS' introduction into the stream of interstate commerce.

295. At all relevant times, Imerys Talc knew or should have known of the unreasonably dangerous and carcinogenic nature of the talc it was selling to the Johnson & Johnson Defendants,

especially when applied to a woman's perineal regions, and it knew or should have known that the Johnson & Johnson Defendants were not warning consumers of this danger.

296. At all relevant times, Imerys Talc knew or should have known that the use of the PRODUCTS significantly increases the risk of ovarian cancer in women based upon scientific knowledge dating back until at least 1971.

297. At all relevant times, the PRODUCTS were defective and unreasonably dangerous when used in a reasonably foreseeable manner because, despite Imerys Talc's knowledge that the PRODUCTS were carcinogenic and could lead to an increased risk of ovarian cancer, Imerys Talc failed to provide adequate warning and/or instruction to consumers, including Plaintiffs, regarding the increased risk of ovarian cancer associated with the use of the PRODUCTS when applied to the perineal area.

298. Had Plaintiffs received warning or instruction regarding the increased risk of ovarian cancer associated with the PRODUCTS when applied to the perineal area, Plaintiffs would not have used the PRODUCTS in this manner.

299. Due to the absence of any warning or instruction by the Defendants as to the significant health and safety risks posed by the PRODUCTS as described herein, Plaintiffs were unaware that the PRODUCTS created an increased risk of ovarian cancer, as this danger was not known to the general public.

300. As a direct and proximate result of Imerys Talc's failure to warn Plaintiffs of the increased risk of ovarian cancer associated with the PRODUCTS when applied to the perineal area, despite its actual knowledge of this material fact, Plaintiffs have suffered and will continue to suffer damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT II - STRICT LIABILITY-FAILURE TO WARN
(Against The Johnson & Johnson Defendants)

301. Plaintiffs incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the individual Plaintiffs' resident State.

302. The Johnson & Johnson Defendants are liable under a theory of strict products liability as set forth in § 402A of the Restatement of Torts (Second).

303. At all relevant times, the Johnson & Johnson Defendants were engaged in the business of manufacturing, formulating, designing, marketing, testing, promoting, selling, distributing, and otherwise introducing into the stream of interstate commerce the PRODUCTS.

304. At all relevant times, the Johnson & Johnson Defendants knew or should have known that the use of the PRODUCTS in the female perineal area significantly increased the risk of ovarian cancer in women based upon scientific knowledge dating back until at least 1971.

305. At all relevant times, the PRODUCTS, manufactured and supplied by the Johnson & Johnson Defendants, were defective and unreasonably dangerous because, despite the Johnson & Johnson Defendants' knowledge that the PRODUCTS were carcinogenic and lead to an increased risk of ovarian cancer when applied to the female perineal area, a reasonably foreseeable use of the PRODUCTS, the Johnson & Johnson Defendants failed to provide adequate warning or instruction to consumers, including Plaintiffs, regarding the increased risk of ovarian cancer when the PRODUCTS are applied to the female perineal area.

306. At all relevant times, Plaintiffs used the PRODUCTS to powder their perineal area, a use that was reasonably foreseeable and for which the PRODUCTS were supplied.

307. Had Plaintiffs received warning and/or instruction from the Johnson & Johnson Defendants regarding the increased risk of ovarian cancer associated with the PRODUCTS when applied to the perineal area, Plaintiffs would not have used the PRODUCTS in this manner.

308. Due to the absence of any warning or instruction by the Johnson & Johnson Defendants as to the significant health and safety risks posed by the PRODUCTS as described herein, Plaintiffs were unaware that the PRODUCTS created an increased risk of ovarian cancer, as this danger was not known to the general public.

309. As the direct and proximate result of the reasonably foreseeable use of the PRODUCTS as manufactured, formulated, marketed, tested, promoted, sold, distributed and introduced into the stream of commerce by the Johnson & Johnson Defendants, Plaintiffs suffered and will continue to suffer damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT III – STRICT LIABILITY –DEFECTIVE MANUFACTURE AND DESIGN (Against Imerys Talc)

310. Plaintiffs incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the individual Plaintiffs' resident State.

311. Imerys Talc is liable under the theory of strict liability as set forth in the Restatement (Second) of Torts § 402A.

312. At all relevant times, Defendant Imerys Talc was engaged in the business of mining and distributing talcum to the Johnson & Johnson Defendants for use in the PRODUCTS, and Imerys Talc was knowingly an integral part of the overall manufacture, design and production of the PRODUCTS, and their introduction into the stream of interstate commerce.

313. At all relevant times, the PRODUCTS were expected to and did reach Plaintiffs without a substantial change in their condition.

314. At all relevant times, the PRODUCTS were defectively and improperly manufactured and designed by Imerys Talc in that, when Imerys Talc supplied its talc product to

the Johnson & Johnson Defendants with full knowledge that the Johnson & Johnson Defendants would use the talc in formulating the PRODUCTS, and that the talc would be the primary ingredient in the PRODUCTS, the foreseeable risks of the PRODUCTS far outweighed the benefits associated with their design and formulation.

315. At all relevant times, the PRODUCTS were defectively manufactured and designed by Imerys Talc in that their design and formulation were more dangerous than an ordinary consumer would expect when used in an intended and reasonably foreseeable manner.

316. At all relevant times, the PRODUCTS created significant risks to the health and safety of consumers that far outweigh the risks posed by other products on the market used for the same therapeutic purpose.

317. As a direct and proximate result of the defective design and manufacture of the PRODUCTS, Plaintiffs suffered and will continue to suffer damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT IV – STRICT LIABILITY –DEFECTIVE MANUFACTURE AND DESIGN
(Against The Johnson & Johnson Defendants)

318. Plaintiffs incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the individual Plaintiffs' resident State.

319. The Johnson & Johnson Defendants are liable under the theory of strict liability as set forth in the Restatement (Second) of Torts § 402A.

320. At all relevant times, the Johnson & Johnson Defendants were engaged in the business of manufacturing, formulating, creating, designing, testing, labeling, packaging, supplying, marketing, promoting, selling, advertising and otherwise introducing the PRODUCTS

into the stream of interstate commerce, which they sold and distributed throughout the United States.

321. At all relevant times, the PRODUCTS were expected to and did reach Plaintiffs without a substantial change in condition.

322. At all relevant times, the PRODUCTS were defectively and improperly manufactured and designed by the Johnson & Johnson Defendants in that, when the PRODUCTS left the hands of the Johnson & Johnson Defendants, the foreseeable risks of the PRODUCTS far outweighed the benefits associated with their design and formulation.

323. At all relevant times, the PRODUCTS were defectively manufactured and designed by the Johnson & Johnson Defendants in that their design and formulation was more dangerous than an ordinary consumer would expect when used in an intended and reasonably foreseeable manner.

324. At all relevant times, the PRODUCTS created significant risks to the health and safety of consumers that far outweigh the risks posed by other products on the market used for the same therapeutic purpose.

325. At all relevant times, a reasonable and safer alternative design existed, which could have feasibly been employed by the Johnson & Johnson Defendants to manufacture a product with the same therapeutic purpose as the PRODUCTS. Despite knowledge of this reasonable and safer alternative design, the Johnson & Johnson Defendants failed to alter the PRODUCTS' design and formulation. The magnitude of the danger created by the PRODUCTS far outweighs the costs associated with using an alternative, safer design.

326. As a direct and proximate result of the defective design and manufacture of the PRODUCTS, Plaintiffs have suffered and will continue to suffer damages for which they are

entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT V- BREACH OF EXPRESS WARRANTIES
(Against The Johnson & Johnson Defendants)

327. Plaintiffs incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the individual Plaintiffs' resident State.

328. The Johnson & Johnson Defendants, through their advertising and promotional materials, expressly warranted and affirmed that the PRODUCTS were safe for the uses for which they were intended and for uses which were reasonably foreseeable. The Johnson & Johnson Defendants' express warranties extended beyond delivery of the PRODUCTS and expressly warranted the future performance of the PRODUCTS. These express warranties include, but are not limited to, the following:

a. The Johnson & Johnson Defendants advertised and labeled the PRODUCTS as safe for application all over the body, including the following: "For you, use every day to help feel soft, fresh, and comfortable;" "A sprinkle a day keeps the odor away;" "Your body perspires in more places than just under your arms;" "Use SHOWER to SHOWER to feel dry, fresh, and comfortable throughout the day;" and "SHOWER to SHOWER can be used all over your body."

b. The Johnson & Johnson Defendants advertised SHOWER to SHOWER to be applied around or on the perineal area. For example, the Johnson & Johnson Defendants advertised that women should use SHOWER to SHOWER to "Soothe Your Skin: Sprinkle on problem areas to soothe skin that has been irritated from friction. Apply after a bikini wax to help reduce irritation and discomfort."

329. The Johnson & Johnson Defendants, through the advertisements as listed above, made express warranties to Plaintiffs and the public that the PRODUCTS were safe and effective when applied all over the body, including the female perineal area.

330. At all relevant times, the Johnson & Johnson Defendants breached said express warranties in that the PRODUCTS were unsafe and ineffective for application all over the body, specifically when used in the female perineal area, because the PRODUCTS, when used in this manner for which the Johnson & Johnson Defendants advertised and promoted, significantly increased the risk of developing ovarian cancer among consumers.

331. At all relevant times, the Johnson & Johnson Defendants had knowledge of the hazards and health risks posed by the PRODUCTS when applied to the perineal area.

332. At all relevant times, the Johnson & Johnson Defendants willfully failed to disclose the defects and health risks of the PRODUCTS to Plaintiffs and the consuming public.

333. At all relevant times, in reliance upon the express warranties made by the Johnson & Johnson Defendants as set forth above, Plaintiffs purchased and used the PRODUCTS in their perineal area, believing that the PRODUCTS were safe when used in this manner.

334. As a direct and proximate result of the Johnson & Johnson Defendants' express warranties concerning the PRODUCTS, as described herein, Plaintiffs suffered and continue to suffer from the injuries and damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT VI – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
(Against The Johnson & Johnson Defendants)

335. Plaintiffs incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the individual plaintiffs' resident State.

336. At the time the Johnson & Johnson Defendants manufactured, marketed, labeled, promoted, distributed and/or sold the PRODUCTS, Defendants knew of the uses for which the PRODUCTS were intended, including use by women in the perineal area, and impliedly warranted the PRODUCTS were merchantable and fit for the ordinary purposes for which they were intended.

337. Members of the consuming public, including consumers such as Plaintiffs, were intended third-party beneficiaries of the warranty.

338. The PRODUCTS were not merchantable or fit for their ordinary purposes, because they had a propensity to lead to the serious personal injuries described herein.

339. Plaintiffs reasonably relied on the Johnson & Johnson Defendants' representations that the PRODUCTS were safe and free of defects.

340. The Johnson & Johnson Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiffs' injuries.

341. The Johnson & Johnson Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems, and suppressed this knowledge from Plaintiffs and the general public. The Johnson & Johnson Defendants made conscious decisions not to redesign, relabel, warn or inform Plaintiffs or the unsuspecting consuming public. The Johnson & Johnson Defendants' outrageous conduct warrants an award of punitive damages.

342. As a direct and proximate result of the Johnson & Johnson Defendants' implied warranties of merchantability concerning the PRODUCTS, as described herein, Plaintiffs suffered and continue to suffer from the injuries and damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT VII – BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE
(Against The Johnson & Johnson Defendants)

343. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles including the law of the Plaintiffs' resident State.

344. The Johnson & Johnson Defendants manufactured, supplied and sold the PRODUCTS with an implied warranty that they were fit for the particular purpose for which they were warranted.

345. Members of the consuming public, including Plaintiffs, were the intended third-party beneficiaries of the warranty.

346. The PRODUCTS were not fit for the particular purpose for which they were warranted without serious risk of personal injury, which risk is much higher than other products designed to perform the same function.

347. Plaintiffs reasonably relied on the Johnson & Johnson Defendants' representations that the PRODUCTS were safe and effective for use by women in the perineal area.

348. The Johnson & Johnson Defendants' breach of the implied warranty of fitness for a particular purpose was the direct and proximate cause of Plaintiffs' injuries.

349. The Johnson & Johnson Defendants' conduct, as described above, was extreme and outrageous. The Johnson & Johnson Defendants risked the lives of the consumers and users of their products, including Plaintiffs, by having knowledge of the safety and efficacy problems associated with the PRODUCTS, but suppressing this knowledge from the general public. The Johnson & Johnson Defendants made conscious decisions not to redesign, relabel, warn or inform

the unsuspecting consuming public. The Johnson & Johnson Defendants' outrageous conduct warrants an award of punitive damages.

350. As a direct and proximate result of the Johnson & Johnson Defendants' implied warranties of fitness concerning the PRODUCTS, as described herein, Plaintiffs suffered and continue to suffer from the injuries and damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT VIII - NEGLIGENCE
(Against Imerys Talc)

351. Plaintiffs incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the individual Plaintiffs' resident State.

352. At all relevant times, Imerys Talc mined, refined, screened, tested and sold talc to the Johnson & Johnson Defendants, which it knew that the Johnson & Johnson Defendants were then packaging and selling to consumers as the PRODUCTS, and that consumers of the PRODUCTS were using it to powder their perineal regions.

353. At all relevant times, Imerys Talc had a duty to act with reasonable care in the design, development, marketing, labeling, manufacturing, formulating, testing, monitoring and sale of the PRODUCTS.

354. At all relevant times, Imerys Talc knew or should have known of the unreasonably dangerous and carcinogenic nature of the talc it was selling to the Johnson & Johnson Defendants, especially when used in a woman's perineal regions, and it knew or should have known that the Johnson & Johnson Defendants did not warn its consumers of that danger.

355. At all relevant times, Imerys Talc was negligent in supplying talc to the Johnson & Johnson Defendants, when it knew or should have known that the talc would be used in the PRODUCTS, without adequately taking steps to ensure that consumers of the PRODUCTS, including Plaintiffs, received material information that Imerys Talc possessed on carcinogenic properties of talc, including its risk of causing ovarian cancer.

356. At all relevant times, Imerys Talc breached its duty of reasonable care to Plaintiffs in that it negligently designed, developed, marketed, labeled, manufactured, formulated, tested, monitored and/or sold talc to the Johnson & Johnson Defendants.

357. As a direct and proximate result of Imerys Talc's negligence, Plaintiffs have suffered and will continue to suffer from injuries and damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT IX - NEGLIGENCE
(Against the Johnson & Johnson Defendants)

358. Plaintiffs incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the individual Plaintiffs' resident State.

359. At all relevant times, the Johnson & Johnson Defendants manufactured, designed, formulated, marketed, tested, promoted, supplied, sold and/or distributed the PRODUCTS in the regular course of business.

360. At all relevant times, the Johnson & Johnson Defendants had a duty to act with reasonable care in the design, development, marketing, labeling, manufacturing, formulating, testing, monitoring, distribution and sale of the PRODUCTS.

361. At all relevant times, the Johnson & Johnson Defendants had a duty to act with reasonable care and to warn Plaintiffs and the consuming public of the risk, dangers and adverse side effects of the PRODUCTS.

362. At all relevant times, the Johnson & Johnson Defendants knew or should have known that the PRODUCTS were unreasonably dangerous and defective when used in a reasonably foreseeable manner.

363. The Johnson & Johnson Defendants breached their duty to Plaintiffs and were otherwise negligent in the design, development, marketing, labeling, manufacturing, formulating, testing, monitoring, distribution and/or sale of the PRODUCTS utilized by Plaintiffs, which were inherently dangerous and defective, and unfit and unsafe for their intended and reasonably foreseeable uses.

364. The Johnson & Johnson Defendants were further negligent in failing to accompany the PRODUCTS with proper warnings or adequate labeling regarding the dangerous and potentially fatal health risks associated with the use of the PRODUCTS, particularly when used in the perineal area of women, which was their intended or reasonable foreseeable use.

365. As a direct and proximate result of the Johnson & Johnson Defendants' negligence, Plaintiffs have suffered and will continue to suffer from injuries and damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT X - NEGLIGENCE
(Against PCPC)

366. Plaintiffs incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs plead all Counts of this Second Amended Master Long Form

Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the individual Plaintiffs' resident State.

367. At all relevant times, PCPC was a national trade association representing the personal care and cosmetics industry of which the Johnson & Johnson Defendants and Imerys Talc were active members.

368. At all relevant times, upon information and belief, the purpose and intent of PCPC was to interact with and influence local, state and federal governmental agencies on issues related to, among other things, the regulation and marketing of talc-based body powders and the PRODUCTS.

369. At all relevant times, PCPC had actual knowledge of the significant risk of ovarian cancer caused by application of talc, talc-based body powders and the PRODUCTS to the female perineal area.

370. At all relevant times, PCPC voluntarily undertook a duty of care to Plaintiffs by self-regulating the cosmetics industry by promulgating federal, state and local standards, norms and/or bylaws that govern, control and/or inform the manufacturing, design, labeling, marketing, distribution and/or branding practices of its member companies, including but not limited to the Johnson & Johnson Defendants and Imerys Talc.

371. At all relevant times, PCPC undertook efforts to disseminate information about talc, talc-based body powder and the PRODUCTS to the consuming public, including Plaintiffs, that it knew or should have known was false and/or misleading and that would result in injury or damages to Plaintiffs.

372. At all relevant times, PCPC had a duty to act with reasonable care in marketing and disseminating information about talc, talc-based body powder and the PRODUCTS to consumers, including Plaintiffs.

373. At all relevant times, PCPC had the means and authority to control the federal, state and local safety standards of the Johnson & Johnson Defendants and Imerys Talc in the manufacturing, design, labeling, marketing, distribution and/or branding of talc, talc-based body powder and the PRODUCTS.

374. At all relevant times, PCPC had the means and authority to control the information about talc and the PRODUCTS it was disseminating to the consuming public regarding the manufacturing, design, labeling, marketing, distribution and/or branding of talc, talc-based body powders and the PRODUCTS.

375. PCPC breached its duty of care to Plaintiffs and the consuming public by negligently failing to ensure that the Johnson & Johnson Defendants and Imerys Talc complied with and adhered to the PCPC standards, norms and/or bylaws concerning the safe manufacture, design, labeling, marketing, distribution and/or branding of talc, talc-based body powders and the PRODUCTS, and subsequently allowing the talc, talc-based body powders and PRODUCTS to be introduced into the federal, state and local streams of interstate commerce despite their significant health and safety risks of which PCPC had full knowledge.

376. PCPC breached its duty of care to Plaintiffs and the consuming public by negligently disseminating information to the consuming public that it knew or should have known was false and/or misleading, and subsequently allowing the talc, talc-based body powders and PRODUCTS to be introduced into the federal, state and local streams of interstate commerce despite their significant health and safety risks of which PCPC had full knowledge.

377. PCPC engaged in activities for the unlawful purpose of promoting its private and commercial interests, the interests of its member companies and talc, specifically, talc-based body powder and the PRODUCTS. PCPC's coordinated efforts, specifically designed to influence the regulation and marketing of talc, talc-based body powder and the PRODUCTS on a local, state

and national level, facilitated conduct which had no legitimate purpose. PCPC's conduct constituted a sham and therefore takes PCPC outside the purview of *Noerr-Pennington* immunity or similar immunities.

378. As a direct and proximate result of PCPC's negligence, the Johnson & Johnson Defendants and Imerys Talc manufactured, designed, labeled, marketed, distributed and branded talc, talc-based body powders and the PRODUCTS on a federal, state and local level in a way that foreseeably caused a significant risk of ovarian cancer when the talc, talc-based body powders and/or the PRODUCTS were applied to the female perineal area.

379. As a direct and proximate result of PCPC's negligence, the marketplace into which the Johnson & Johnson Defendants and Imerys Talc introduced their talc, talc-based body powders and the PRODUCTS, was void of fair and balanced information regarding the significant risk of ovarian cancer when the talc, talc-based body powders and/or the PRODUCTS were applied to the female perineal area.

380. As a further direct and proximate result of PCPC's negligence, Plaintiffs suffered and will continue to suffer from injuries and damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT XI – NEGLIGENT MISREPRESENTATION
(Against the Johnson & Johnson Defendants)

381. Plaintiffs incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs plead all Counts of this Second Amended Master Long Form

Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the individual Plaintiffs' resident State.

382. At all relevant times, the Johnson & Johnson Defendants were engaged in the business of manufacturing, formulating, marketing, testing, promoting, selling and/or distributing the PRODUCTS.

383. At all relevant times, the Johnson & Johnson Defendants had a duty to disclose to consumers and the public material facts about the PRODUCTS, including the material fact that application of the PRODUCTS to the female perineal area causes a significantly increased risk of ovarian cancer.

384. Through their actions and omissions in advertising, promoting, labeling and otherwise, the Johnson & Johnson Defendants made public misrepresentations of material facts to, and/or concealed material facts from, consumers like Plaintiffs concerning the character, safety and effectiveness of the PRODUCTS.

385. At all relevant times, those misrepresentations and omissions included, but were not limited to, the following:

a. The Johnson & Johnson Defendants labeled and advertised the PRODUCTS in the following ways, among others: "For you, use every day to help feel soft, fresh, and comfortable;" "A sprinkle a day keeps the odor away;" "Your body perspires in more places than just under your arms;" "Use SHOWER to SHOWER to feel dry, fresh, and comfortable throughout the day; and "SHOWER to SHOWER can be used all over your body."

b. The Johnson & Johnson Defendants advertised the product SHOWER to SHOWER to be applied "all over," and in particular, urged women to use it to

"Soothe Your Skin: Sprinkle on problem areas to soothe skin that has been irritated from friction. Apply after a bikini wax to help reduce irritation and discomfort."

c. The Johnson & Johnson Defendants, through the advertisements described above, among others, misrepresented to consumers, including Plaintiffs, that the PRODUCTS were safe for use all over the body, including the female perineal area.

d. The Johnson & Johnson Defendants misrepresented to consumers, including Plaintiffs, that the PRODUCTS did not contain asbestos, heavy metals, or fibrous talc.

e. Despite actual knowledge of the health risks of the PRODUCTS, the Johnson & Johnson Defendants failed to disclose to the consumers and Plaintiffs, through adequate warnings, representations, labeling or otherwise, that the PRODUCTS were inherently dangerous and carcinogenic in nature, which poses serious health risks to consumers.

f. Despite actual knowledge that the use of the PRODUCTS in the perineal area created a significantly increased risk of ovarian cancer, the Johnson & Johnson Defendants failed to disclose to consumers, including Plaintiffs, through adequate warnings, representations, labeling or otherwise, that material fact.

386. At all relevant times, the Johnson & Johnson Defendants failed to exercise reasonable care in ascertaining or sharing information regarding the safe use of the PRODUCTS, failed to disclose facts indicating that the PRODUCTS were inherently dangerous and carcinogenic in nature, and otherwise failed to exercise reasonable care in communicating the information concerning the PRODUCTS to Plaintiffs and/or concealed relevant facts that were known to them.

387. At all relevant times, Plaintiffs were not aware of the falsity of the foregoing misrepresentations, nor were they aware that material facts concerning talc and the PRODUCTS had been concealed or omitted. In reasonable reliance upon the Johnson & Johnson Defendants' misrepresentations and/or omissions, Plaintiffs were induced to and did purchase the PRODUCTS and did use the PRODUCTS on their perineal areas. If the Johnson & Johnson Defendants had disclosed true and accurate material facts concerning the risks of the use of the PRODUCTS, in particular the risk of developing ovarian cancer from using the PRODUCTS in the female perineal area, Plaintiffs would not have purchased and/or received the PRODUCTS and/or used the PRODUCTS in that manner.

388. Plaintiffs' reliance upon the Johnson & Johnson Defendants' misrepresentations and omissions were justified and reasonable because, among other reasons, those misrepresentations and omissions were made by individuals and entities who were in a position to know the material facts concerning the PRODUCTS and the association between the PRODUCTS and the incidence of ovarian cancer, while Plaintiffs were not in a position to know these material facts, and because the Johnson & Johnson Defendants failed to warn or otherwise provide notice to the consuming public as to the risks of the PRODUCTS, thereby inducing Plaintiffs to use the PRODUCTS in lieu of safer alternatives and in ways that created unreasonably dangerous risks to their health. At all relevant times, the Johnson & Johnson Defendants' corporate officers, directors and/or managing agents knew of and ratified the acts of the Johnson & Johnson Defendants, as alleged herein.

389. As a direct and proximate result of the Johnson & Johnson Defendants' negligent misrepresentations and/or omissions concerning the risks and benefits of the PRODUCTS, Plaintiffs suffered and continue to suffer from the injuries and damages for which they are entitled

to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT XII - FRAUD
(Against the Johnson & Johnson Defendants)

390. Plaintiffs incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the individual Plaintiffs' resident State.

391. At all relevant times, the Johnson & Johnson Defendants intentionally, willfully and/or recklessly, with the intent to deceive, misrepresented and/or concealed material facts to consumers and users, including Plaintiffs.

392. At all relevant times, the Johnson & Johnson Defendants misrepresented and/or concealed material facts concerning the PRODUCTS to consumers, including the Plaintiffs, with knowledge of the falsity of their misrepresentations.

393. At all relevant times, upon information and belief, the misrepresentations and concealments concerning the PRODUCTS made by the Johnson & Johnson Defendants include, but are not limited to the following:

a. The Johnson & Johnson Defendants falsely labeled and advertised the PRODUCTS in the following ways, among others: "For you, use every day to help feel soft, fresh, and comfortable," "a sprinkle a day keeps the odor away," "your body perspires in more places than just under your arms," "Use SHOWER to SHOWER to feel dry, fresh, and comfortable throughout the day," and "SHOWER to SHOWER can be used all over your body."

b. The Johnson & Johnson Defendants falsely advertised SHOWER to SHOWER to be applied "all over," and in particular, urged women to use it to "Soothe Your

Skin: Sprinkle on problem areas to soothe skin that has been irritated from friction. Apply after a bikini wax to help reduce irritation and discomfort."

c. The Johnson & Johnson Defendants, through the advertisements described above, knowingly misrepresented to Plaintiffs and the public that the PRODUCTS were safe for use all over the body, including the perineal areas of women.

d. The Johnson & Johnson Defendants intentionally failed to disclose that talc and the associated PRODUCTS, when used in the perineal area, increase the risk of ovarian cancer.

e. The Johnson & Johnson Defendants intentionally failed to disclose and actively concealed that talcum powder products contained other carcinogenic constituents such as fibrous talc, asbestos, heavy metals, and fragrance chemicals.

f. The Johnson & Johnson Defendants intentionally failed to include adequate warnings with the PRODUCTS regarding the potential and actual risks of using the PRODUCTS in the perineal area on women and the nature, scope, severity and duration of any serious injuries resulting therefrom.

g. Despite knowing about the carcinogenic nature of talc and its likelihood to increase the risk of ovarian cancer in women, the Johnson & Johnson Defendants falsely marketed, advertised, labeled and sold the PRODUCTS as safe for public consumption and usage, including for use by women to powder their perineal areas.

394. At all relevant times, the Johnson & Johnson Defendants actively, knowingly and intentionally concealed and misrepresented these material facts to the consuming public with the intent to deceive the public and Plaintiffs, and with the intent that consumers would purchase and use the PRODUCTS in the female perineal area.

395. At all relevant times, the consuming public, including Plaintiffs, would not otherwise have purchased the PRODUCTS and/or applied the PRODUCTS in the perineal area if they had been informed of the risks associated with the use of the PRODUCTS in the perineal area.

396. At all relevant times, Plaintiffs relied on the Johnson & Johnson Defendants' misrepresentations concerning the safety of the PRODUCTS when purchasing the PRODUCTS and using the PRODUCTS on their perineal areas, and their reliance was reasonable and justified.

397. As a direct and proximate result of the Johnson & Johnson Defendants' fraudulent conduct concerning the PRODUCTS, as described herein, Plaintiffs suffered and continue to suffer from the injuries and damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT XIII - FRAUD
(Against PCPC)

398. Plaintiffs incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the individual Plaintiffs' resident State.

399. At all relevant times, PCPC intentionally, willfully and/or recklessly, with the intent to deceive, misrepresented and/or concealed material facts to consumers and users of talc-based body powders and the PRODUCTS, including Plaintiffs.

400. At all relevant times, PCPC intentionally, willfully and/or recklessly, with the intent to deceive, misrepresented and/or concealed materials facts to local, state and federal regulators in order to unduly influence the regulation and marketing of talc, talc-based body powders and the PRODUCTS. The actions of PCPC on a local, state and federal level impacted

what material facts were or could be disclosed to consumers and users of talc-based body powders and the PRODUCTS, including Plaintiffs.

401. At all relevant times, PCPC, on a local, state and federal level, fraudulently misrepresented and/or concealed material facts to consumers and users of the PRODUCTS, including Plaintiffs, with knowledge of the falsity of their misrepresentations.

402. At all relevant times, PCPC fraudulently misrepresented and/or concealed materials facts to local, state and federal regulators in order to unduly influence the regulation and marketing of talc, talc-based body powders and the PRODUCTS. The fraudulent actions of PCPC on a local, state and federal level impacted what material facts were or could be disclosed to consumers and users of talc-based body powders and the PRODUCTS, including Plaintiffs.

403. At all relevant times, upon information and belief, PCPC's conduct giving rise to fraud includes, but is not limited, to the following:

a. PCPC formed the TIPTF, with the purpose of self-regulating the talc industry and to pool financial resources in an effort to prevent regulation of talc, including talc-based body powders and the PRODUCTS.

b. PCPC, through the TIPTF, hired and funded scientists to perform research regarding the safety of talc. The TIPTF then edited the scientific reports in an effort to skew the data so that it demonstrated safety of talc and talc-based body powder and suppressed data demonstrating these dangers. The TIPTF then released and disseminated this biased and intentionally misleading data to local, state and federal governmental agencies, with the intent that the biased and intentionally misleading data would influence material facts that were or could be disclosed to consumers of talc, talc-based body powders and the PRODUCTS, including Plaintiffs.

c. PCPC, through the TIPTF, knowingly released false information about the safety of talc-based body powder to the consuming public with the intent to induce consumers, including the Plaintiffs, to purchase talc-based body powders.

d. PCPC extensively lobbied and used political and economic influence on local, state and federal governmental bodies in order to prevent regulation of talc-based body powder, including the PRODUCTS. These efforts were based knowingly on false and misleading information about the safety of talc and talc-based body powder.

e. PCPC caused to be released, published and disseminated, medical and scientific data, literature and reports containing information and statements regarding the risks of ovarian cancer which PCPC knew were incorrect, incomplete and misleading.

f. PCPC's action impacted the perceptions about the safety of talc and talc-based body powder in the public domain in a manner that falsely made it appear as though the PRODUCTS were safe and that their use did not pose a risk for women of contracting cancer of the reproductive system. PCPC's actions contaminated and falsely influenced the risk /benefit information available in the public domain to the detriment of consumers, including the Plaintiffs.

404. At all relevant times, PCPC actively, knowingly and intentionally concealed and misrepresented these material facts to consumers, including Plaintiffs, with the intent to deceive the public and Plaintiffs, and with the intent that consumers would purchase and use talc-based body powder and the PRODUCTS in the female perineal area.

405. At all relevant times, PCPC actively, knowingly and intentionally misrepresented these material facts to local, state and federal governmental agencies with the intent to deceive these agencies and influence material facts conveyed to consumers, including Plaintiffs, with the

intent that consumers would purchase and use talc-based body powder and the PRODUCTS in the female genital area.

406. The consuming public, including Plaintiffs, would not have purchased talc-based body powders and/or the PRODUCTS and/or applied talc-based body powders and/or the PRODUCTS in the perineal area if they had been informed of the risks associated with the use of the PRODUCTS in that manner.

407. At all relevant times, Plaintiffs relied on PCPC's self-regulation of and misrepresentations concerning the safety of talc-based body powders and the PRODUCTS and PCPC's fraudulent conduct when purchasing talc-based body powders and/or the PRODUCTS and using them in their perineal areas, and their reliance was reasonable and justified.

408. PCPC engaged in, coordinated or facilitated conduct with no legitimate purpose, and used various improper means to achieve unlawful ends, such that its conduct constituted a sham and therefore takes PCPC outside the purview of *Noerr-Pennington* immunity or similar immunities.

409. As a direct and proximate result of PCPC's fraudulent conduct concerning talc-based body powder and the PRODUCTS, as described herein, Plaintiffs suffered and continue to suffer from the injuries and damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT XIV – VIOLATION OF CONSUMER PROTECTION LAWS
(Against The Johnson & Johnson Defendants)

410. Plaintiffs incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the individual Plaintiffs' resident State.

411. Plaintiffs purchased and used the PRODUCTS primarily for personal use and thereby suffered ascertainable losses as a result of the Johnson & Johnson Defendants' actions in violation of the consumer protection laws applicable to the individual Plaintiffs' resident State.

412. Unfair methods of competition or deceptive acts or practices that were proscribed by law, include the following:

a. Representing that goods or services have characteristics, ingredients, user benefits or qualities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised;

c. Over-promotion of the PRODUCTS, including but not limited to over-promotion of their safety and efficacy; and

d. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

413. The Johnson & Johnson Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of the PRODUCTS.

414. The Johnson & Johnson Defendants uniformly communicated the purported benefits of the PRODUCTS while failing to disclose the serious and dangerous risk of ovarian cancer related to the use of the PRODUCTS, especially use in the perineal area, and of the true state of the PRODUCTS' safety, efficacy and usefulness. The Johnson & Johnson Defendants made these representations to consumers, including Plaintiffs, in the marketing and advertising described herein. The Johnson & Johnson Defendants' conduct in connection with the PRODUCTS was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because the Johnson & Johnson Defendants misleadingly, falsely and/or

deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, safety, efficacy and advantages of the PRODUCTS.

415. As a result of these violations of consumer protection laws, Plaintiffs have incurred damage and other expenses, for which the Johnson & Johnson Defendants are liable.

416. As a direct and proximate result of the Johnson & Johnson Defendants' violation of consumer protection laws concerning the PRODUCTS, as described herein, Plaintiffs suffered and continue to suffer from the damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT XV – FRAUDULENT CONCEALMENT
(Against Imerys Talc)

417. Plaintiffs incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the individual Plaintiffs' resident State.

418. Prior to Plaintiffs' use of the PRODUCTS and during the period in which plaintiffs actually used the PRODUCTS, Imerys Talc fraudulently suppressed material information regarding the safety and efficacy of the PRODUCTS and the availability of an alternative feasible safer design, including but not limited to, information regarding a safe use of cornstarch based products for the same purposes. Furthermore, Imerys Talc fraudulently concealed the safety information about the use of talc, generally, and on the perineal area, specifically. Plaintiffs believe the fraudulent misrepresentations and fraudulent concealment described throughout this Second Amended Master Long Form Complaint were intentional so as to maintain the sales volume of its talc.

419. Imerys Talc intentionally concealed safety issues with talc generally in order to induce consumers, including Plaintiffs, to purchase the PRODUCTS.

420. At the time Imerys Talc concealed the fact that the PRODUCTS were not safe as designed and marketed by the Johnson & Johnson Defendants, Imerys Talc was under a duty to communicate this information to the general public in such a manner that the general public would appreciate the risks associated with using the PRODUCTS, generally.

421. Plaintiffs relied upon the Defendants' false and fraudulent misrepresentations and concealments regarding the safety of the PRODUCTS.

422. As a direct and proximate result of Imerys Talc's malicious and intentional concealment of material and information, Defendants caused or significantly contributed to Plaintiffs' injuries.

423. Imerys Talc furthered this fraudulent concealment through a continued and systematic failure to disclose information to Plaintiffs and the public.

424. Imerys Talc's conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Imerys Talc must have realized was dangerous, needless and reckless, without regard to the consequences or the rights and safety of Plaintiffs.

425. As a direct and proximate result of Imerys Talc's fraudulent concealment concerning the PRODUCTS, as described herein, Plaintiffs suffered and continue to suffer from the damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT XVI – FRAUDULENT CONCEALMENT
(Against The Johnson & Johnson Defendants)

426. Plaintiffs incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs plead all Counts of this Second Amended Master Long Form

Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the individual Plaintiffs' resident State.

427. Prior to Plaintiffs' use of the PRODUCTS and during the period in which Plaintiffs actually used the PRODUCTS, the Johnson & Johnson Defendants fraudulently suppressed material information regarding the safety and efficacy of the PRODUCTS and the availability of an alternative feasible safer design, including but not limited to, information regarding the safe use of cornstarch based products for the same purposes. Furthermore, the Johnson & Johnson Defendants fraudulently concealed the safety information about the use of the PRODUCTS, generally, and on the perineal area, specifically. Plaintiffs believe the fraudulent misrepresentations and fraudulent concealment described throughout this Second Amended Master Long Form Complaint were intentional so as to maintain the sales volume of the PRODUCTS.

428. The Johnson & Johnson Defendants intentionally concealed safety issues with the PRODUCTS in order to induce consumers, including Plaintiffs, to purchase the PRODUCTS.

429. At the time the Johnson & Johnson Defendants concealed the fact that the PRODUCTS were not safe as designed and marketed, the Johnson & Johnson Defendants were under a duty to communicate this information to the general public in such a manner that the general public could appreciate the risks associated with using the PRODUCTS, generally.

430. Plaintiffs relied upon the Defendants' false and fraudulent misrepresentations and concealments regarding the safety of the PRODUCTS.

431. As a direct and proximate result of the Johnson & Johnson Defendants' malicious and intentional concealment of material and information, the Johnson & Johnson Defendants caused or significantly contributed to Plaintiffs' injuries.

432. The Johnson & Johnson Defendants furthered this fraudulent concealment through a continued and systematic failure to disclose information to Plaintiffs and the public.

433. The Johnson & Johnson Defendants' acts before, during and/or after the act causing Plaintiffs' injuries prevented Plaintiffs from discovering the injury or cause thereof.

434. The Johnson & Johnson Defendants' conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which the Johnson & Johnson Defendants must have realized was dangerous, needless and reckless, without regard to the consequences or the rights and safety of Plaintiffs.

435. As a direct and proximate result of the Johnson & Johnson Defendants' fraudulent concealment concerning the PRODUCTS, as described herein, Plaintiffs suffered and continue to suffer from the damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT XVII – FRAUDULENT CONCEALMENT
(Against PCPC)

436. Plaintiffs incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the individual Plaintiffs' resident State.

437. Prior to Plaintiffs' use of the PRODUCTS and during the period in which Plaintiffs actually used the PRODUCTS, PCPC fraudulently suppressed material information regarding the safety and efficacy of talc-based body powders and the PRODUCTS and the availability of an alternative feasible safer design, including but not limited to, information regarding a safe use of cornstarch based products for the same purposes. Furthermore, PCPC fraudulently concealed the safety information about the use of talc, generally, and talc-based body powder on the perineal area, specifically. Plaintiffs believe the fraudulent misrepresentations and fraudulent concealment

described throughout this Second Amended Master Long Form Complaint was intentional so as to maintain the sales volume of talc, talc-based body powders and the PRODUCTS.

438. PCPC fraudulently suppressed material information from the consuming public, local, state and federal government agencies regarding the safety and efficacy of talc-based body powders and the PRODUCTS and the availability of an alternative feasible safer design, including but not limited to, information regarding a safe use of cornstarch based products for the same purposes. Furthermore, PCPC fraudulently concealed the safety information about the use of talc, generally, and the application of talc-based body powder to the female genital area, specifically.

439. PCPC intentionally concealed safety issues with talc-based body powders, generally, in order to induce consumers, including plaintiffs, to purchase the PRODUCTS.

440. At the time PCPC concealed the fact that talc-based body powders and the PRODUCTS were not safe as designed and marketed by the Johnson & Johnson Defendants, PCPC was under a duty to communicate this information to local, state and federal agencies, as well as the general public, in such a manner that the general public could appreciate the risks associated with using the PRODUCTS, generally.

441. Plaintiffs relied upon the Defendants' false and fraudulent misrepresentations and concealments regarding the safety of talc-based body powders and the PRODUCTS when used in the female genital area.

442. PCPC engaged in, coordinated or facilitated conduct with no legitimate purpose, and used various improper means to achieve unlawful ends, such that its conduct constituted a sham and therefore takes PCPC outside the purview of *Noerr-Pennington* immunity or similar immunities.

443. As a direct and proximate result of PCPC's malicious and intentional concealment of material and information, PCPC caused or significantly contributed to Plaintiffs' injuries.

444. PCPC furthered this fraudulent concealment through a continued and systematic failure to disclose information to local, state and federal government agencies, Plaintiffs and the public.

445. PCPC's acts before, during and/or after the act causing Plaintiffs' injuries prevented Plaintiffs from discovering the injury or cause thereof.

446. PCPC's conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which PCPC must have realized was dangerous, needless and reckless, without regard to the consequences or the rights and safety of Plaintiffs.

447. As a direct and proximate result of PCPC's fraudulent concealment concerning the PRODUCTS, as described herein, Plaintiffs suffered and continue to suffer from injuries and damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT XVIII – CIVIL CONSPIRACY
(Against All Defendants)

448. Plaintiffs incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the individual Plaintiffs' resident State.

449. At all relevant times, the Defendants and/or their predecessors-in-interest knowingly agreed, contrived, combined, confederated, acted in concert, aided and abetted and/or conspired to cause Plaintiffs' injuries by exposing Plaintiffs to the PRODUCTS, which are harmful and dangerous.

450. Further, at all relevant times, the Defendants knowingly agreed, contrived, confederated, acted in concert, aided and abetted and/or conspired to defraud Plaintiffs and

consumers of the PRODUCTS regarding the true nature of the PRODUCTS and their potential to cause ovarian cancer when used in a reasonably foreseeable manner.

451. At all relevant times, the Defendants knowingly agreed, contrived, confederated, acted in concert, aided and abetted and/or conspired to defraud Plaintiffs and consumers of the PRODUCTS with the purpose of maintaining the popularity and reputation of the PRODUCTS and, therefore, maintaining high sales of the PRODUCTS, at the expense of consumer safety.

452. At all relevant times, pursuant to and in furtherance of said conspiracies, the Defendants performed the following overt and unlawful acts:

a. For many decades, upon information and belief, Defendants, individually, jointly, and in conspiracy with each other, have been in possession of medical and scientific data, literature and test reports which indicate that, when applied to the perineal area, an ordinary and foreseeable use by women, talc-based body powder and the PRODUCTS are unreasonably dangerous, hazardous, deleterious to human health, carcinogenic and potentially deadly;

b. Upon information and belief, despite the medical and scientific data, literature and test reports possessed by and available to the Defendants, Defendants individually, jointly and in conspiracy with each other, fraudulently, willfully and maliciously:

i. Withheld, concealed and suppressed said medical information regarding the increased risk of ovarian cancer from consumers, including Plaintiffs;

ii. Withheld, concealed and suppressed information regarding the presence of fibrous talc, asbestos, heavy metals, and fragrance chemicals in the PRODUCTS;

iii. Through the TIPTF, Defendants instituted a "defense strategy" to defend talc-based body powder at all costs. Admittedly, the Defendants, through

the TIPTF, used their influence over the NTP Subcommittee, and the threat of litigation against the NTP, to prevent the NTP from classifying talc as a carcinogen on its 10th RoC;

iv. Defendants, through the TIPTF, used their influence over local, state and federal agencies to control material facts disclosed to consumers, including Plaintiffs; and

v. Caused to be released, published and disseminated medical and scientific data, literature, and test reports containing information and statements regarding the risks of ovarian cancer, which Defendants knew were incorrect, incomplete and misleading.

c. Upon information and belief, by these false and fraudulent representations, omissions and concealments, Defendants intended to induce consumers, including Plaintiffs, to rely upon said false and fraudulent representations, omissions and concealments, and to continue to expose themselves to the dangers inherent in the use of talc-based body powders and the PRODUCTS.

453. Plaintiffs reasonably relied upon the aforementioned fraudulent representations, omissions and concealments made by the Defendants regarding the nature of talc-based body powder and the PRODUCTS.

454. PCPC engaged in, coordinated or facilitated conduct with no legitimate purpose, and used various improper means to achieve unlawful ends, such that its conduct constituted a sham and therefore takes PCPC outside the purview of *Noerr-Pennington* immunity or similar immunities.

455. As a direct and proximate result of Defendants' overt unlawful acts regarding the nature of talc-based baby powder and the PRODUCTS which were made pursuant to and in

furtherance of a common scheme, and Plaintiffs' reliance thereon, Plaintiffs suffered and continue to suffer from the injuries and damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorney fees.

COUNT XIX - LOSS OF CONSORTIUM
(Against All Defendants)

456. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the law of the Plaintiffs' resident State.

457. At all relevant times hereto, Plaintiffs had spouses (hereafter referred to as "Spouse Plaintiffs") and/or family members (hereafter referred to as "Family Member Plaintiffs") who have suffered injuries and losses as a result of the PRODUCTS and Plaintiffs' injuries.

458. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment, monitoring, medications and other expenditures, and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

459. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

460. For all Spouse Plaintiffs, Plaintiffs allege that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered.

461. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

462. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs, Family Member Plaintiffs and/or intimate partners of the aforesaid Plaintiffs, have

sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs, Family Member Plaintiffs and intimate partners jointly and severally for all general, special and equitable relief to which Spouse Plaintiffs, Family Member Plaintiffs and intimate partners are entitled by law.

COUNT XX - PUNITIVE DAMAGES
(Against All Defendants)

463. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles including the law of the Plaintiffs' resident State.

464. Defendants sold the PRODUCTS to Plaintiffs and other consumers throughout the United States without doing adequate testing to ensure that the PRODUCTS were reasonably safe for their intended use.

465. Defendants sold the PRODUCTS to Plaintiffs and other consumers throughout the United States in spite of their knowledge that the PRODUCTS cause the problems heretofore set forth in this Second Amended Master Long Form Complaint, thereby causing the severe and debilitating injuries suffered by the Plaintiffs.

466. At all times relevant hereto, Defendants knew or should have known that the PRODUCTS were inherently dangerous with respect to the risk of ovarian cancer, loss of life's enjoyment, an effort to cure the conditions proximately related to the use of the PRODUCTS, as well as other severe and personal injuries which are permanent and lasting in nature.

467. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the PRODUCTS, including but not limited to

information regarding the increased risk of developing ovarian cancer when the PRODUCTS are used in the perineal area.

468. Defendants' misrepresentations included knowingly withholding material information from the consumers, including Plaintiffs, concerning the safety and efficacy of the PRODUCTS.

469. At all times material hereto, Defendants knew and intentionally and/or recklessly disregarded the fact that the PRODUCTS cause debilitating and potentially lethal side effects with greater frequency than safer alternative products.

470. At all times material hereto, Defendants knew and intentionally and/or recklessly disregarded the fact that the PRODUCTS cause debilitating and potentially lethal side effects with greater frequency than safer alternative products and recklessly failed to advise the public of the same.

471. At all times material hereto, Defendants intentionally misstated and misrepresented data, and continue to misrepresent data, so as to minimize the true and accurate risk of injuries and complications caused by the PRODUCTS.

472. Notwithstanding the foregoing, Defendants continue to aggressively market the PRODUCTS to consumers, without disclosing the true risk of side effects.

473. Defendants knew that the PRODUCTS were defective and of an unreasonably dangerous nature, but continued to manufacture, produce, assemble, market, distribute and sell the PRODUCTS so as to maximize sales and profits at the expense of the health and safety of the Public, including Plaintiffs, in conscious and/or reckless disregard of the foreseeable harm caused by the PRODUCTS.

474. Defendants continue to intentionally conceal and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiffs, the serious side effects of the PRODUCTS in order to ensure continued and increased sales.

475. Defendants' intentional, reckless and/or grossly negligent failure to disclose information deprived Plaintiffs of necessary information to enable them to weigh the true risks of using the PRODUCTS against their benefits.

476. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require health care and services, and have incurred medical, health care, incidental and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care and/or hospital care and medical services.

477. Defendants have engaged in conduct entitling Plaintiffs to an award of punitive damages pursuant to Common Law principles and the statutory provisions of the Plaintiffs' respective states.

478. Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

COUNT XXI - WRONGFUL DEATH
(Against All Defendants)

479. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles including the law of the Plaintiffs' resident State.

480. Plaintiffs Decedents' spouses, beneficiaries and/or lawful representatives of Decedents' Estates bring this claim on behalf of themselves and as the Decedents' lawful beneficiaries.

481. As a direct and proximate result of the conduct of the Defendants and the defective nature of the PRODUCTS as outlined above, Decedents suffered bodily injury resulting in pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses for hospitalization, medical and nursing treatment, loss of earnings, loss of ability to earn, funeral expenses and death.

482. As a direct and proximate cause of the conduct of Defendants, Decedents' beneficiaries have incurred hospital, nursing and medical expenses, and estate administration expenses as a result of Decedents' deaths. Plaintiffs, Administrators of Decedents' estates, bring this claim on behalf of Decedents' lawful beneficiaries for these damages and for all pecuniary losses sustained by said beneficiaries pursuant to any and all relevant statutes.

483. As a direct and proximate result of Defendants' overt unlawful acts regarding the nature of the PRODUCTS, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, damages for wrongful death, together with interest, costs of suit, attorneys' fees, punitive damages and such further relief as the Court deems equitable and just.

COUNT XXII - SURVIVAL ACTION
(Against All Defendants)

484. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Second Amended Master

Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles including the law of the Plaintiffs' resident State.

485. As a direct and proximate result of the conduct of Defendants, Decedents, prior to their deaths, were obligated to spend various sums of money to treat their injuries, which debts have been assumed by their estates. As a direct and proximate cause of the aforesaid, Decedents were caused pain and suffering, mental anguish and impairment of the enjoyment of life, until the date of their deaths and, as a direct and proximate result of the aforesaid, Decedents suffered a loss of earnings and earning capacity. Plaintiffs' spouses, as Administrators of the Estates of Decedents, bring this claim on behalf of the estates for damages under any and all applicable statute or common law.

486. As a direct and proximate result of the conduct of Defendants, Decedents and their spouses, until the time of Decedents' deaths, suffered a disintegration and deterioration of the family unit and the relationships existing therein, resulting in enhanced anguish, depression and other symptoms of psychological stress and disorder. This claim is brought on behalf of the Estates of the Decedents pursuant to any and all applicable statutes or common law.

487. As a direct and proximate result of the conduct of Defendants, and including the observances of the suffering of the Decedents, until the date of their deaths, Plaintiffs suffered permanent and ongoing psychological damage.

488. As a direct and proximate result of the aforesaid, and including the observance of the suffering and physical deterioration of Decedents until the date of their deaths, Plaintiffs have and will continue to suffer permanent and ongoing psychological damage which may require future psychological and medical treatment. Plaintiffs' spouses, as Administrators of the Estates of the Decedents, bring the claims on behalf of the Estates for damages any and all applicable statutes or common law and in their own right.

489. Defendants' actions, as described above, were performed willfully, intentionally, and with reckless disregard for the rights of the Plaintiffs and the public.

490. As a result of the Defendants' conduct, the Plaintiffs suffered the injuries and damages specified herein.

491. Accordingly, the Plaintiffs seek and are entitled to compensatory and punitive damages in an amount to be determined at trial.

492. As a direct and proximate result of Defendants' overt unlawful acts regarding the nature of the PRODUCTS, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, damages for wrongful death, together with interest, costs of suit, attorneys' fees, punitive damages and such further relief as the Court deems equitable and just.

COUNT XXIII – SPOLIATION
(Against the Johnson & Johnson Defendants and PCPC)
(Alaska, Connecticut, New Mexico, Ohio, & West Virginia Plaintiffs)

493. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to the laws of Alaska, Connecticut, New Mexico, Ohio, and West Virginia.

494. At least since 1971, Defendants J&J, J&J Consumer, and PCPC had a duty to preserve relevant evidence even though litigation had not commenced because Defendants knew litigation related to the PRODUCTS was probable at some point in the future.

495. As described above, Defendants J&J, J&J Consumer, and PCPC intentionally destroyed relevant evidence despite knowledge of the potential for future litigation and the need to preserve the evidence.

496. Defendants J&J, J&J Consumer, and PCPC intentionally destroyed the code keys corresponding to the tables with asbestos test results from "round robin" testing conducted in 1977.

497. Defendants J&J and J&J Consumer destroyed documents created or produced in prior litigation related to talc.

498. Defendants J&J and J&J Consumer (or outside laboratories contracted by J&J) failed to preserve any talc samples, including TEM grids, it tested for asbestos content from the 1950s to the 2000s.

499. Defendants J&J and J&J Consumer (or its outside laboratories at their direction) failed to preserve count sheets, photomicrographs, and other documentation generated during the testing of talc samples for asbestos and other fibers from the 1950s to the 2000s.

500. Plaintiffs have been damaged as a result of Defendants' intentional spoliation because the absence of the spoliated evidence limits Plaintiffs' ability to present and prove their cases.

DISCOVERY RULE AND TOLLING

501. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Second Amended Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles including the law of the Plaintiffs' resident State.

502. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

503. Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence

should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

504. Despite diligent investigation by Plaintiffs into the cause of their injuries, the nature of Plaintiffs' injuries and damages and their relationship to the PRODUCTS was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

505. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendant(s) are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and/or the consuming public, of the true risks associated with the PRODUCTS. As a result of the Defendants' fraudulent concealment, Plaintiffs and/or Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendant(s).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants on each of the above-referenced claims and causes of action, jointly and severally, as follows:

a. Awarding compensatory damages in excess of $75,000, including, but not limited to pain, suffering, discomfort, physical impairment, physical disfigurement, fear of cancer recurrence or death, emotional distress, loss of enjoyment of life, loss of consortium, wrongful death and other noneconomic damages in an amount to be determined at trial of this action;

b. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determined at trial of this action;

c. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and Decedent in an amount sufficient to punish Defendants and deter future similar conduct;

d. Prejudgment interest;

e. Post-judgment interest;

f. Awarding reasonable attorneys' fees;

g. Awarding the costs of these proceedings; and

h. Such other and further relief as this Court deems just and proper.

Dated: December 9, 2020

RESPECTFULLY SUBMITTED,

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